**IN THE UNITED STATES DISTRICT COURT**
**FOR THE NORTHERN DISTRICT OF ILLINOIS**
**EASTERN DIVISION**

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| ERIC HESTRUP, individually and on behalf of all others similarly situated,<br><br>*Plaintiff*,<br><br>v.<br><br>MALLINCKRODT PLC; MALLINCKRODT LLC; MALLINCKRODT ENTERPRISES, LLC; MALLINCKRODT BRAND PHARMACEUTICALS, INC.; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS, INC.; ACTAVIS PLC; ACTAVIS, INC.; WATSON PHARMACEUTICALS, INC.; WATSON LABORATORIES, INC.; MCKESSON CORPORATION; CARDINAL HEALTH, INC.; and AMERISOURCEBERGEN CORPORATION,<br><br>*Defendants*. | Case No. 1:19-cv-08453<br><br>**CLASS ACTION COMPLAINT**<br><br>**JURY TRIAL DEMANDED** |

## CLASS ACTION COMPLAINT AND DEMAND FOR JURY TRIAL


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Plaintiff Eric Hestrup ("Plaintiff") is a natural person and resident of Illinois. Plaintiff brings this Class Action Complaint ("Complaint") against Mallinckrodt plc, Mallinckrodt LLC, Mallinckrodt Enterprises, LLC, Mallinckrodt Brand Pharmaceuticals, Inc., Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., Cephalon, Inc., Johnson & Johnson, Janssen Pharmaceuticals, Inc., Endo Health Solutions Inc., Endo Pharmaceuticals, Inc., Actavis plc, Actavis, Inc., Watson Pharmaceuticals, Inc., and Watson Laboratories, Inc. (collectively, "Manufacturer Defendants"); McKesson Corporation, Cardinal Health, Inc., and AmerisourceBergen Corporation (collectively, with Mallinckrodt plc, Mallinckrodt LLC, Mallinckrodt Enterprises, LLC, and Mallinckrodt Brand Pharmaceuticals, Inc., "Distributor Defendants") (all together, "Defendants"), seeking redress for Defendants' alleged illegal acts that have caused Plaintiff's health insurance premiums to increase. Plaintiff, for his Complaint, alleges as follows upon personal knowledge as to himself and his own acts and experiences and, as to all other matters, upon information and belief, including investigation conducted by his attorneys.

## INTRODUCTION

1. Prescription opioids have devastated communities in every part of the country. Since 1999, there have been more than 183,000 reported opioid-related deaths nationwide—more than three times the number of U.S. soldiers who died in the Vietnam War. In addition to the tragic loss of life and the heartbreaking impact on children and loved ones, some estimates state that the opioid crisis is costing governmental entities and private companies as much as $500 billion per year.

2. Defendants manufacture, market, sell, and distribute prescription opioids, which are powerful, highly addictive narcotic painkillers. The Manufacturer Defendants and Related

Unnamed Parties have engaged in a cunning and deceptive marketing scheme to encourage doctors and patients to use opioids to treat chronic pain. In doing so, the Manufacturer Defendants and Related Unnamed Parties falsely minimized the risks of opioids, overstated their benefits, and generated far more opioid prescriptions than there should have been.

3. The opioid epidemic is the direct result of the Manufacturer Defendants' and Related Unnamed Parties' deliberately crafted, well-funded campaign of deception. For years, they misrepresented the risks posed by the opioids they manufacture and sell, misleading susceptible prescribers and vulnerable patient populations. As families and communities suffered from the scourge of opioid abuse, the Manufacturer Defendants and Related Unnamed Parties earned billions in profits as a direct result of the harms they imposed.

4. The Manufacturer Defendants and Related Unnamed Parties knew that their misrepresentations about the risks and benefits of opioids were not supported by, and sometimes were directly contrary to, the scientific evidence. Certain opioid manufacturers, including Defendants Mallinckrodt and Endo, and Related Unnamed Party Purdue, have entered agreements prohibiting them from making misrepresentations identified in this Complaint in some jurisdictions. Despite these promises, the Manufacturer Defendants and Related Unnamed Parties continue to misrepresent the risks and benefits of long-term opioid use throughout the nation, and they have not corrected their past misrepresentations.

5. The Manufacturer Defendants' and Related Unnamed Parties' false and misleading statements deceived doctors and patients about the risks and benefits of opioids and convinced them that opioids were not only appropriate, but *necessary* to treat chronic pain. The Manufacturer Defendants and Related Unnamed Parties targeted susceptible prescribers, like family doctors, and vulnerable patient populations, like the elderly and veterans. And they

tainted the sources that doctors and patients relied upon for guidance, including treatment guidelines, medical education programs, medical conferences and seminars, and scientific articles. As a result, they successfully transformed the way doctors treat chronic pain, opening the floodgates of opioid prescriptions and dependence. Opioids are now the most prescribed class of drugs, generating billions of dollars in revenue for the Manufacturer Defendants and Related Unnamed Parties every year.

6. In addition, the Distributor Defendants could and should have prevented the brunt of the opioid epidemic, but instead allowed the country to be flooded with prescription opioids. Under federal law, distributors are required to secure and monitor drugs as they travel through commerce, to protect them from theft, and to reject and report suspicious or unusual orders by downstream pharmacies, doctors, or patients. But the Distributor Defendants neglected this duty, turning a blind eye to known or knowable problems in their own supply chains. By doing so, the Distributor Defendants created conditions in which vast amounts of opioids flowed freely from the Manufacturer Defendants and Related Unnamed Parties to abusers and drug dealers—with the Distributors Defendants readily fulfilling suspicious orders from pharmacies and ignoring red flags that would require further investigation and resolution.

7. This behavior by the Distributor Defendants has allowed massive amounts of opioids to be diverted from legitimate channels of distribution into the illicit black market, fueling the opioid epidemic. The Distributor Defendants created an environment in which drug diversion can flourish. For years, the Distributor Defendants have had the ability to substantially reduce the death toll and adverse economic consequences of opioid diversion but opted to pursue corporate revenues instead. All of the Defendants in this action share responsibility for creating, sustaining, and prolonging the opioid epidemic.

8. The explosion in opioid prescriptions and use has created a public health crisis in the United States. An oversupply of prescription opioids has provided a source for illicit use or sale of opioids, while their widespread use has created a population of addicted and dependent patients. When those patients can no longer afford or legitimately obtain opioids, they often turn to the street to buy prescription opioids or even heroin. In addition to the societal impact of deaths, overdoses, and rampant addiction, Defendants' conduct has created higher demand and thus higher prices for opioids, as well as the need for expensive medical treatment for a number of covered health conditions, resulting in increased insurance costs for United States residents.

9. Defendants' conduct has fueled skyrocketing opioid addiction and opioid-related deaths and emergency treatments, and has generated huge sales of opioids at inflated prices.

10. The direct and proximate consequence of Defendants' misconduct is that every United States purchaser of private health insurance has paid higher premiums, co-payments, and deductibles. Insurance companies have considerable market power and pass onto their insureds the expected cost of future care—including opioid-related coverage. Accordingly, insurance companies factored in the unwarranted and exorbitant health care costs of opioid-related coverage caused by Defendants and charged that back to insureds in the form of higher premiums, deductibles, and co-payments.

11. This action seeks to hold Defendants accountable for the economic harm they have imposed on United States purchasers of private health insurance.

## PARTIES

12. Plaintiff Eric Hestrup is a natural person and resident and citizen of the State of Illinois.

13. Mallinckrodt, plc is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri. Mallinckrodt, LLC and Mallinckrodt Enterprises LLC are limited liability companies organized and existing under the laws of the State of Delaware with their principal places of business in St. Louis, Missouri. Since June 28, 2013, Mallinckrodt, LLC has been a wholly owned subsidiary of Mallinckrodt, plc. Prior to June 28, 2013 Mallinckrodt, LLC was a wholly-owned subsidiary of Covidien plc. Mallinckrodt Brand Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware with its principal place of business in Hazelwood, Missouri. Mallinckrodt plc, Mallinckrodt LLC, Mallinckrodt Enterprises, LLC, and Mallinckrodt Brand Pharmaceuticals, Inc. are referred to as "Mallinckrodt."

14. Mallinckrodt manufactures and markets two branded opioids: Exalgo, which is extended-release hydromorphone, sold in 8, 12, 16, and 32 mg dosage strengths, and Roxicodone, which is oxycodone, sold in 15 and 30 mg dosage strengths. In 2009, Mallinckrodt Inc. acquired the U.S. rights to Exalgo. The Food and Drug Administration ("FDA") approved Exalgo for treatment of chronic pain in 2012. Exalgo was designed with properties to make it harder to abuse, but it has not been approved by the FDA to make abuse-deterrent claims. Exalgo is still sold and marketed today. Mallinckrodt further expanded its branded opioid portfolio in 2012 by purchasing Roxicodone from Xanodyne Pharmaceuticals. In addition, Mallinckrodt developed Xartemis XR, an extended- release combination of oxycodone and acetaminophen, which the FDA approved in March 2014, and which Mallinckrodt discontinued in August 2015. Mallinckrodt promoted its branded opioid products with its own direct sales force.

15. While it has sought to develop its branded opioid products, Mallinckrodt has long been a leading manufacturer of generic opioids. Mallinckrodt estimated that in 2015 it received

the right to produce approximately 25% of the U.S. Drug Enforcement Administration's ("DEA") entire annual quota for controlled substances. Mallinckrodt also estimated, based on IMS Health data for the same period, that its generics claimed an approximately 23% market share of DEA Schedules II and III opioid and oral solid dose medications.

16. Mallinckrodt operates a vertically integrated business in the United States: (1) importing raw opioid materials, (2) manufacturing specialty branded and generic opioid products, (3) marketing and selling its products to drug distributors, specialty pharmaceutical distributors, retail pharmacy chains, pharmaceutical benefit managers that have mail-order pharmacies, and hospital buying groups; and (4) distributing opioids through its own supply chain.

17. In 2017, Mallinckrodt entered into a settlement with the DEA after their investigation revealed that "Mallinckrodt knew about the diversion [of oxycodone] and sold excessive amounts of the most highly abused forms of oxycodone, 30 mg and 15 mg tablets, placing them into a stream of commerce that would result in diversion." To settle these claims, Mallinckrodt paid a fine of $35 million.

18. Defendant Cephalon, Inc. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. Defendant Teva Pharmaceutical Industries, Ltd. ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petah Tikva, Israel. In 2011, Teva Ltd. acquired Cephalon, Inc. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a wholly owned subsidiary of Teva Ltd. and is incorporated in Delaware with its principal place of business in North Wales, Pennsylvania.

19. Cephalon, Inc. manufactures, promotes, sells, and distributes opioids such as Actiq and Fentora in the United States.

20. Teva Ltd., Teva USA, and Cephalon, Inc. work together closely to market and sell Cephalon products in the United States. Teva Ltd. conducts all sales and marketing activities for Cephalon in the United States through Teva USA and has done so since its October 2011 acquisition of Cephalon. Teva Ltd. and Teva USA hold out Actiq and Fentora as Teva products to the public. Teva USA sells all former Cephalon branded products through its "specialty medicines" division. The FDA-approved prescribing information and medication guide, which is distributed with Cephalon opioids, discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events.

21. All of Cephalon's promotional websites, including those for Actiq and Fentora, display Teva Ltd.'s logo. Teva Ltd.'s financial reports list Cephalon's and Teva USA's sales as its own, and its year-end report for 2012—the year immediately following the Cephalon acquisition—attributed a 22% increase in its specialty medicine sales to the inclusion of a full year of Cephalon's specialty sales, including *inter alia* sales of Fentora. Through interrelated operations like these, Teva Ltd. operates in the United States through its subsidiaries Cephalon and Teva USA. The United States is the largest of Teva Ltd.'s global markets, representing 53% of its global revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Inc., Teva Ltd. would conduct those companies' business in the United States itself. Upon information and belief, Teva Ltd. directs the business practices of Cephalon and Teva USA, and their profits inure to the benefit of Teva Ltd. as controlling shareholder. Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., and Cephalon, Inc. are referred to as "Cephalon."

22. Defendant Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its principal place of business in New Jersey and is a wholly owned subsidiary of Johnson &

Johnson. Defendant Johnson & Johnson is a New Jersey corporation with its principal place of business in New Jersey.

23. On information and belief, at all relevant times, Janssen Pharmaceuticals, Inc. and Johnson & Johnson (together, "Janssen") acted in concert with one another and acted as agents and/or principals of one another in relation to the conduct described herein.

24. Janssen manufactures, promotes, sells, and distributes drugs in the United States, including the opioid Duragesic. Before 2009, Duragesic accounted for at least $1 billion in annual sales. Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta and Nucynta ER. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014.

25. Defendant Endo Pharmaceuticals Inc. is a Delaware corporation with its principal place of business in Pennsylvania, and is a wholly owned subsidiary of Endo Health Solutions Inc. Defendant Endo Health Solutions Inc. is a Delaware corporation with its principal place of business in Pennsylvania.

26. On information and belief, at all relevant times, Endo Pharmaceuticals Inc. and Endo Health Solutions Inc. (together, "Endo") acted in concert with one another and acted as agents and/or principals of one another in relation to the conduct described herein.

27. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydone, in the United States. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana ER yielded $1.25 billion in revenue from 2009 through 2013, and it accounted for 10% of Endo's total revenue during that period.

28. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the United States, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.

29. On June 8, 2017, the FDA called for Endo to remove Opana ER from the market, concluding that the risks of the drug outweigh its benefits.

30. Allergan plc is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. Defendant Actavis plc acquired Allergan plc in March 2015, and the combined company changed its name to Allergan plc in June 2015. Before that, Defendant Watson Pharmaceuticals, Inc. acquired Defendant Actavis, Inc. in October 2012, and the combined company changed its name to Actavis, Inc. as of January 2013 and then Actavis plc in October 2013.

31. Defendant Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in California, and is a wholly-owned subsidiary of Allergan plc (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.). Actavis Pharma, Inc. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey, and was formerly known as Watson Pharma, Inc. Actavis LLC is a Delaware limited liability company with its principal place of business in New Jersey. Each of these defendants is owned by Allergan plc, which uses them to market and sell its drugs in the United States.

32. Upon information and belief, Allergan plc exercises control over these marketing and sales efforts and profits from the sale of Allergan/Actavis products ultimately inure to its benefit. (Allergan plc, Actavis plc, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. are referred to as "Actavis.")

33. Actavis manufactures, promotes, sells, and distributes opioids, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana, in the United States. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008 and began marketing Kadian in 2009.

34. Defendant McKesson Corporation ("McKesson") is a Delaware corporation with its principal place of business in Texas. McKesson distributes substantial amounts of prescription opioids to providers and retailers in the United States.

35. Defendant Cardinal Health, Inc. ("Cardinal") is an Ohio corporation with its principal place of business in Ohio. Cardinal distributes substantial amounts of prescription opioids to providers and retailers in the United States.

36. Defendant AmerisourceBergen Corporation ("AmerisourceBergen") is a Delaware corporation with its principal place of business in Pennsylvania. AmerisourceBergen distributes substantial amounts of prescription opioids to providers and retailers in the United States.

37. At all relevant times, Defendants promoted, marketed, advertised, distributed and sold opioid products across the United States and to American residents, citizens, and businesses.

**RELATED UNNAMED PARTIES**

38. Defendants are not the only companies that are responsible for the opioid epidemic that is ravishing the United States. Due to the procedural posture of other litigation, certain entities at the center of the opioid epidemic have not been named in this matter. This is purely a mechanism of the automatic stay and court orders in federal bankruptcy courts enjoining any new actions taken against entities with cases pending.

39. Insys Therapeutics, Inc. ("Insys") manufactures, markets, sells and distributes Subsys—a sublingual spray of fentanyl—nationwide. On June 10, 2019, Insys filed for Chapter 11 bankruptcy protection in the U.S. Bankruptcy Court for the District of Delaware[1], just five days after agreeing to pay $225 million to settle the federal government's criminal and civil cases against the company for bribing doctors to prescribe its fentanyl-based painkiller. The filing of the bankruptcy initiated an automatic stay of the commencement or continuation of any litigation claims, pursuant to 11 U.S.C. § 362.

40. Purdue Pharma L.P, Purdue Pharma Inc., and Purdue Frederick Company (together, "Purdue") manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER in the United States. OxyContin is Purdue's best-selling opioid, and it accounts for nearly one-third of the national painkiller market. Since 2009, Purdue's annual sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion.

41. On September 16, 2016, Purdue filed for bankruptcy protection in the U.S. Bankruptcy Court for the Southern District of New York[2] as part of its plan to settle litigation with dozens of states and other plaintiffs who allege the company fueled the opioid crisis, which initiated an automatic stay.[3] In continuation to the imposition of the automatic stay, the Court entered orders on October 11, 2019 and November 6, 2019 pursuant to section § 105(a) of title 11 of the United States Code and Rule 7065 of the Federal Rules of Bankruptcy Procedure to

[1] *In re: Insys Therapeutics Inc. et al*., case number 1:19-bk-11292, in the U.S. Bankruptcy Court for the District of Delaware.
[2] *In re: Purdue Pharma LP*, case number 19-23649, in the U.S. Bankruptcy Court for the Southern District of New York.
[3] 11 U.S.C. § 362.

enjoin the governmental entities and private litigants from the commencement or continuation of their active judicial, administrative, or other actions or proceedings against Purdue.

42. Collectively Insys and Purdue will be called "Related Unnamed Parties."

## JURISDICTION AND VENUE

43. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(d)(2), because (i) at least one member of the putative Class is a citizen of a state different from Defendant Mallinckrodt plc, (ii) the amount in controversy exceeds $5,000,000, exclusive of interest and costs, and (iii) none of the exceptions under the subsection apply to this action.

44. This Court has personal jurisdiction over each Defendant because Plaintiff's claims arise out of, or relate to, each Defendants' contacts with Illinois. For example:

- Defendants knowingly and intentionally sell, market, advertise, promote, and distribute their products in the State of Illinois and to Illinois residents, citizens, and businesses, as well as to the State of Illinois;
- Defendants enter into contracts relating to the subject-matter of this action in the State of Illinois;
- Defendants have directed advertising, marketing, and promotional efforts at the State of Illinois and Illinois residents, citizens, and businesses;
- Defendants have engaged in advertising, marketing, and promotional activities with the intent and expectation that these activities would reach and affect the State of Illinois and/or Illinois residents, citizens, and businesses; and
- Defendants have delivered, distributed, dispensed, and sold opioids in Illinois with the intent and the expectation that those products would be distributed to or purchased by Illinois residents, citizens, and businesses.

45. Venue is proper in this District because a substantial part of the events giving rise to Plaintiff's claims occurred in, were directed to, and/or emanated from this District. 28 U.S.C. § 1391(b).

## FACTUAL ALLEGATIONS

### A. Because Opioids Are Highly Addictive, Prevailing Medical Norms Dictated That

**They Should Not Be Prescribed for Chronic Pain.**

46. Opioids are a class of chemical compounds that bind to opioid receptors in the human nervous system. Opioids elicit a euphoric response by stimulating pleasure centers in the brain. This euphoric response allows opioids to effectively mask pain, but it also causes the drugs to be highly addictive.

47. Common opioids include morphine, methadone, oxycodone, hydrocodone, codeine, and fentanyl. These drugs cannot be lawfully obtained without a valid prescription. Common brand names for these drugs include Vicodin, Percocet, and OxyContin. Heroin is also classified as an opioid.

48. Before the 1990s, generally accepted standards of medical practice dictated that opioids should be used only for cases of acute pain, surgery recovery, cancer treatment, or end-of-life palliative care. There was widespread medical consensus that opioids should not be used to treat chronic pain due to the lack of evidence that opioids improved patients' ability to overcome pain, coupled with evidence of greater pain complaints as patients developed tolerance to opioids over time, and the serious risk of addiction and other side effects.

49. In the limited cases where patients were prescribed opioids, the drugs ordinarily were administered in closely supervised environments, like inpatient-treatment or hospice facilities, and typically only for short periods of time. These closely supervised conditions mitigated the risk that patients might misuse opioids, and they allowed doctors to monitor patients for signs of potential addiction or dependence.

50. While these prevailing medical norms had strong scientific bases and reflected sound medical judgment, the Manufacturer Defendants and Related Unnamed Parties viewed the medical community's hesitance to prescribe opioids as an impediment to substantial profits they could obtain from increased use of their opioid products. Thus, the Manufacturer Defendants

and Related Unnamed Parties devised a scheme to misrepresent the risks and benefits of opioids to increase prescriptions by tapping into the large and lucrative market for chronic-pain patients.

### B. The Manufacturer Defendants and Related Unnamed Parties Disseminate False and Misleading Statements About Opioids.

51. The Manufacturer Defendants and Related Unnamed Parties employed a multi-pronged approach to misinform doctors and patients.

52. ***First***, the Manufacturer Defendants and Related Unnamed Parties communicated directly to doctors and chronic-pain patients. For doctors, this took the form of in-person visits and communications from sales and promotional staff; continuing medical education programs; advertisements, including in periodicals aimed at medical audiences; websites; and other means. For chronic-pain patients, this included websites; advertisements; publications aimed at the public; and other means.

53. For example, the Manufacturer Defendants and Related Unnamed Parties spent more than $14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001. This amount included $4.9 million by Janssen and $1.1 million by Endo.

54. In addition, the Manufacturer Defendants and Related Unnamed Parties promoted the use of opioids for chronic pain through "detailers"—sales representatives who visited individual doctors and medical staff in their offices—and small group speaker programs. These detailers have spread and continue to spread misinformation regarding the risks and benefits of opioids to hundreds of thousands of doctors. Publicly available Open Payments Data[4] shows that in 2017 alone, Defendant Mallinckrodt's sales representatives visited United States prescribers

[4] Open Payments is a federal program that collects information regarding visits and payments to doctors from pharmaceutical and medical device companies. Pharmaceutical and medical device companies are required to disclose this information under the Physician Payments Sunshine Act in the 2010 Affordable Care Act.

tens of thousands of times, in visits that included some sort of payment[5] to the doctor. This number likely understates the amount of "detailing" by Mallinckrodt sales representatives, as it reflects only visits in which a payment was provided. And not until February 2018 did Related Unnamed Party Purdue announce that would will cease the practice of sending its salespeople to visit doctors to promote its opioid drugs.

55. The Manufacturer Defendants and Related Unnamed Parties devoted and continue to devote massive resources to direct sales contacts with doctors. In 2014 alone, they spent $168 million on detailing branded opioids to doctors—twice as much as they spent on detailing in 2000. The amount includes $34 million by Janssen, $10 million by Endo, and $2 million by Actavis.

56. The Manufacturer Defendants' and Related Unnamed Parties' detailing to doctors is effective. Numerous studies indicate that marketing impacts prescribing habits, with face-to-face detailing having the greatest influence. Moreover, more frequent prescribers of opioids across the country are generally more likely to have received a detailing visit.

57. The Manufacturer Defendants' and Related Unnamed Parties' detailers have been reprimanded for their deceptive promotions. For example, a July 2010 "Dear Doctor" letter mandated by the FDA required Actavis to acknowledge to the doctors to whom it marketed its drugs that "[b]etween June 2009 and February 2010, Actavis sales representatives distributed . . . promotional materials that . . . omitted and minimized serious risks associated with [Kadian]," including the risk of "[m]isuse, [a]buse, and [d]iversion of [o]pioids" and, specifically, the risk that "[o]pioid[s] have the potential for being abused and are sought by drug abusers and people with addiction disorders and are subject to criminal diversion."

[5] Payments include activities such as promotional speaking, consulting, travel, and meals.

58. ***Second***, the Manufacturer Defendants and Related Unnamed Parties created, funded, controlled, and operated third-party organizations that communicated directly with doctors and chronic-pain patients to promote opioid use generally without naming specific brands.

59. The Manufacturer Defendants and Related Unnamed Parties marketed through third-party, unbranded advertising to avoid regulatory scrutiny because such advertising is not submitted to and typically is not reviewed by the FDA. They also used third-party, unbranded advertising to give the false appearance that the deceptive messages came from an independent and objective source.

60. The Manufacturer Defendants' and Related Unnamed Parties' deceptive, unbranded marketing often contradicted what they said in their branded materials reviewed by the FDA. For example, Endo's unbranded advertising stated that "People who take opioids as prescribed usually do not become addicted," which contradicted its concurrent, branded advertising for Opana ER, which warned that "use of opioid analgesic products carries the risk of addiction even under appropriate medical use."

61. Under the direction and control of the Manufacturer Defendants and Related Unnamed Parties, these third-party organizations, known as "Front Groups," which include the American Pain Foundation ("APF") and the American Academy of Pain Medicine ("AAPM"), generated treatment guidelines, unbranded materials, and programs that endorsed chronic opioid therapy. These guidelines, materials, and programs were not supported by the evidence at the time they were created, nor are they supported by the scientific evidence today. Indeed, they stand in marked contrast to the CDC's 2016 *Guideline for Prescribing Opioids for Chronic Pain* ("2016 CDC Guideline"). These Front Groups also assisted the Manufacturer Defendants and

Related Unnamed Parties by responding to negative articles, advocating against regulatory changes that would limit opioid prescriptions, and conducting outreach to vulnerable patient populations targeted by the Manufacturer Defendants and Related Unnamed Parties.

62. For example, the Alliance for Patient Access ("APA"), founded in 2006, is a self-described patient advocacy and health professional organization that styles itself as "a national network of physicians dedicated to ensuring patient access to approved therapies and appropriate clinical care."[6] The organization is a Front Group. It is run by Woodberry Associates LLC, a lobbying firm that was also established in 2006.[7] As of January 2018, the APA listed 30 "Associate Members and Financial Supporters," which includes Mallinckrodt.[8]

63. Among its activities, APA issued a "white paper" titled "Prescription Pain Medication: Preserving Patient Access While Curbing Abuse."[9] Among other things, the white paper criticizes prescription monitoring programs,[10] purporting to express concern that they are burdensome, not user friendly, and of questionable efficacy:

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[6] *About AfPA*, The Alliance for Patient Access, http://allianceforpatientaccess.org/ about-afpa/#membership (last visited May 8, 2018). References herein to APA include two affiliated groups: the Global Alliance for Patient Access and the Institute for Patient Access.

[7] Mary Chris Jaklevic, *Non-profit Alliance for Patient Access uses journalists and politicians to push Big Pharma's agenda*, Health News Review (Oct. 2, 2017), https://www.healthnewsreview.org/2017/10/non-profit-alliance-patient-access-uses-journalists- politicians-push-big-pharmas-agenda/ (hereinafter "Jaklevic*, Non-profit Alliance for Patient Access*").

[8] APA's board members, including Dr. Robert A. Yapundich, Dr. Jack D. Schim, and Dr. Howard Hoffberg, have also directly received funding from pharmaceutical companies including Mallinckrodt. *See* ProPublica's Dollars for Docs database, available at https://projects.propublica.org/docdollars/

[9] Prescription Pain Medication: Preserving Patient Access While Curbing Abuse, Institute for Patient Access (Oct. 2013), http://1yh21u3cjptv3xjder1dco9mx5s. wpengine.netdna-cdn.com/wp-content/uploads/2013/12/PT_White-Paper_Finala.pdf

[10] Prescription monitoring programs, such as the St. Louis County Prescription Drug Monitoring Program (or PDMP), serve to curb diversion by providing physicians with access to information regarding prescriptions of controlled substances patients have received during a certain period of time.

Prescription monitoring programs that are difficult to use and cumbersome can place substantial burdens on physicians and their staff, ultimately leading many to stop prescribing pain medications altogether. This forces patients to seek pain relief medications elsewhere, which may be much less convenient and familiar and may even be dangerous or illegal.

* * *

In some states, physicians who fail to consult prescription monitoring databases before prescribing pain medications for their patients are subject to fines; those who repeatedly fail to consult the databases face loss of their professional licensure. Such penalties seem excessive and may inadvertently target older physicians in rural areas who may not be facile with computers and may not have the requisite office staff. Moreover, threatening and fining physicians in an attempt to induce compliance with prescription monitoring programs represents a system based on punishment as opposed to incentives. . . .

We cannot merely assume that these programs will reduce prescription pain medication use and abuse.[11]

[11] Prescription Pain Medication: Preserving Patient Access While Curbing Abuse, Institute for

64. The white paper also purports to express concern about policies that have been enacted in response to the prevalence of pill mills:

> Although well intentioned, many of the policies designed to address this problem have made it difficult for legitimate pain management centers to operate. For instance, in some states, [pain management centers] must be owned by physicians or professional corporations, must have a Board certified medical director, may need to pay for annual inspections, and are subject to increased record keeping and reporting requirements. . . . [I]t is not even certain that the regulations are helping prevent abuses.[12]

65. In addition, in an echo of earlier industry efforts to push back against what they termed "opiophobia," the white paper laments the stigma associated with prescribing and taking pain medication:

> Both pain patients and physicians can face negative perceptions and outright stigma. When patients with chronic pain can't get their prescriptions for pain medication filled at a pharmacy, they may feel like they are doing something wrong—or even criminal. . . . Physicians can face similar stigma from peers. Physicians in non- pain specialty areas often look down on those who specialize in pain management—a situation fueled by the numerous

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Patient Access (Oct. 2013), http://1yh21u3cjptv3xjder1dco9mx5s. wpengine.netdna-cdn.com/wp-content/uploads/2013/12/PT_White-Paper_Finala.pdf.

[12] *Id.* at 5-6.

regulations and fines that surround prescription pain medications.[13]

66. In conclusion, the white paper advocates for the use of opioids for chronic pain, stating, "[p]rescription pain medications, and specifically the opioids, can provide substantial relief for people who are recovering from surgery, afflicted by chronic painful diseases, or experiencing pain associated with other conditions that does not adequately respond to over-the-counter drugs."[14]

67. The APA also lobbies Congress directly. In 2015, the APA signed onto a letter supporting legislation proposed to limit the ability of the DEA to police pill mills by enforcing the "suspicious orders" provision of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. §801 et seq. ("CSA" or "Controlled Substances Act").[15] An internal U.S. Department of Justice ("DOJ") memo stated that the proposed bill "'could actually result in increased diversion, abuse, and public health and safety consequences'"[16] and, according to DEA Chief Administrative Law Judge John J. Mulrooney, the law would make it "all but logically impossible" to prosecute manufacturers and distributors, like Mallinckrodt here, in federal courts.[17] The law passed both houses of Congress and was signed into law in 2016. These efforts

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[13] *Id.* at 6.
[14] *Id.* at 7.
[15] Letter from Alliance for Patient Access, et al., to Congressmen Tom Marino, Marsha Blackburn, Peter Welch, and Judy Chu (Jan. 26, 2015), http://www.hoparx.org/images/hopa/advocacy/advocacy-activities/FINAL_Patient_Access_Letter_of_Support_House_Bill.pdf.
[16] Bill Whitaker, Ex-DEA Agent: Opioid Crisis Fueled by Drug Industry and Congress, CBS News (Oct. 17, 2017), https://www.cbsnews.com/news/ ex-dea-agent-opioid-crisis-fueled- by-drug-industry-and-congress/ (hereinafter, "Whitaker, Opioid Crisis Fueled by Drug Industry").
[17] John J. Mulrooney, II & Katherine E. Legel, Current Navigation Points in Drug Diversion Law: Hidden Rocks in Shallow, Murky, Drug-Infested Waters, 101 Marquette L. Rev. (forthcoming Feb. 2018), https://www.documentcloud.org/ documents/4108121-Marquette-Law- Review-Mulrooney-Legel.html.

to prevent the implementation of programs and statutes that are designed to prevent diversion are in direct contravention of Mallinckrodt's public claims that it is committed to fighting opioid misuse and preventing diversion.

68. The U.S. Pain Foundation ("USPF") was another Front Group with systematic connections and interpersonal relationships with Manufacturer Defendants and Related Unnamed Parties. The USPF was one of the largest recipients of contributions from the Mallinckrodt and other opioid makers, collecting nearly $3 million from opioid makers in payments between 2012 and 2015 alone. The USPF was also a critical component of Mallinckrodt's lobbying efforts to reduce the limits on over-prescription. The USPF advertises its ties to Defendant Mallinckrodt, listing opioid manufacturers like Mallinckrodt, as "Platinum," "Gold," and "Basic" corporate members.[18] Industry Front Groups like the American Academy of Pain Management, the American Academy of Pain Medicine, the American Pain Society, and PhRMA are also members of varying levels in the USPF.

69. The USPF has made several misleading statements regarding opioids. For example, USPF claims that opioid treatment allows patients to function.[19] Additionally, Paul Gileno, the founder and president of the USPF, claimed that opioids allow people to "participate in daily life and be contributing members of society."[20] The USPF made further misleading statements, including statements that involve veterans. For example, the USPF website discusses recent opioid prescribing guidelines released by the Department of Veteran Affairs and Department of Defense. The USPF describe these guidelines as "problematic" due to their

[18] *Id*. at 12; Transparency, U.S. Pain Foundation, https://uspainfoundation.org/transparency/ (last accessed on March 9, 2018).
[19] U.S. Pain Foundation, New Coalition Calls for Balanced Approach to Opioids, available at https://uspainfoundation.org/news/new-coalition-calls-balanced-aproach-opioids/.
[20] *Id.*

advice to prescribe 20-50 morphine milligram equivalents ("MME") per day with caution, and their warning against prescribing more than 90 MEEs per day. The group also suggests untreated chronic pain creates a risk of suicide, and therefore physicians should not necessarily be cautious in prescribing opioids to those with suicidal ideation.[21]

70. These Front Groups depended on the Manufacturer Defendants and Related Unnamed Parties for funding. As a result, the Manufacturer Defendants and Related Unnamed Parties exercised control over programs and materials created by these groups by collaborating on, editing, and approving their content, and by funding their dissemination. Purdue's consulting agreement with APF, for example, gave it direct control over APF's work. The Manufacturer Defendants and Related Unnamed Parties thus ensured that the Front Groups would disseminate only the messages that the Manufacturer Defendants and Related Unnamed Parties wanted to promote. Nonetheless, the Front Groups held themselves out as independent and serving the needs of their members—whether patients suffering from pain, or the doctors treating those patients.

71. Through the Front Groups, the Manufacturer Defendants and Related Unnamed Parties conspired to spread their deceptive messages about the risks and benefits of long-term opioid therapy. For example, Manufacturer Defendants and Related Unnamed Parties combined their efforts through the Pain Care Forum ("PCF"), which APF started in 2004. PCF is composed of representatives from opioid manufacturers (including Endo, Janssen, and Purdue) and various Front Groups, almost all of which received substantial funding from the Manufacturer Defendants and Related Unnamed Parties. Among other projects, PCF worked to

[21] U.S. Pain Foundation, VA Restricts Opioids for Veterans and Military Service Members, available at https://uspainfoundation.org/news/va-restricts-opioids-veteran/.

ensure that an FDA-mandated education project on opioids was not too negative and did not require mandatory participation by prescribers, which the Manufacturer Defendants and Related Unnamed Parties feared would reduce prescriptions. PCF also worked to address a perceived "lack of coordination" among its members and developed "key" messages that were disseminated in programs and industry-run websites.

72. At all relevant times, the Manufacturer Defendants and Related Unnamed Parties controlled, operated, funded, and acted in concert with APA, APF, AAPM, and other Front Groups. The Manufacturer Defendants and Related Unnamed Parties provided substantial funding for these organizations' activities. In 2010 alone, APF received more than $1 million from Defendant Endo, more than $100,000 from Purdue, as well as substantial contributions from Defendant Janssen.

73. At all relevant times, the Manufacturer Defendants and Related Unnamed Parties were legally responsible for the acts, omissions, and representations of APA, APF, and AAPM; APA, APF, and AAPM acted as agents for Defendants; and Defendants conspired with APA, APF, AAPM, and other third-party entities with respect to the conduct described herein.

74. ***Third***, the Manufacturer Defendants and Related Unnamed Parties enlisted highly credentialed medical professionals to spread their false narratives about the risks and benefits of opioids and other pain-treatment options. These medical professionals engaged by the Manufacturer Defendants and Related Unnamed Parties have been referred to as "key opinion leaders" or "KOLs," who include individuals such as Dr. Russell Portenoy and Dr. Lynn Webster.

75. Because these KOLs purported to act independently, the purpose and effect of their involvement was to lend legitimacy to the Manufacturer Defendants' and Related Unnamed

Parties' false and misleading claims about opioids. The Manufacturer Defendants and Related Unnamed Parties paid these KOLs to serve as consultants or on their advisory boards and to give talks or to present continuing medical education programs (CMEs), and their support helped these KOLs become respected industry experts. As they rose to prominence, these KOLs touted the benefits of opioids to treat chronic pain, repaying the Manufacturer Defendants and Related Unnamed Parties by advancing their marketing goals. KOLs' professional reputations became dependent on continuing to promote a pro-opioid message, even in activities that were not directly funded by the Manufacturer Defendants and Related Unnamed Parties.

76. Pro-opioid doctors are one of the most important avenues that the Manufacturer Defendants and Related Unnamed Parties have used to spread their false and misleading statements about the risks and benefits of long-term opioid use. The Manufacturer Defendants and Related Unnamed Parties know that doctors rely heavily on their peers for guidance, and KOLs provide the false appearance of unbiased and reliable support for chronic opioid therapy. For example, the New York Attorney General ("NY AG") found in its 2015 settlement with Purdue that, through March 2015, the Purdue website *In the Face of Pain* failed to disclose that doctors who provided testimonials on the site were paid by Purdue. The NY AG concluded that Purdue's failure to disclose these financial connections potentially misled consumers regarding the objectivity of the testimonials.

77. KOLs have written, consulted on, edited, and lent their names to books and articles, and given speeches and CMEs, supportive of chronic opioid therapy. The Manufacturer Defendants and Related Unnamed Parties created opportunities for KOLs to participate in research studies that the Manufacturer Defendants and Related Unnamed Parties proposed or selected, and then cited and promoted favorable studies or articles by their KOLs.

78. Not surprisingly, the Manufacturer Defendants and Related Unnamed Parties did not support or disseminate publications of doctors unsupportive or critical of chronic opioid therapy.

79. The KOLs also served on committees that developed treatment guidelines that strongly encourage the use of opioids to treat chronic pain and on the boards of pro-opioid advocacy groups and professional societies that develop, select, and present CMEs. These guidelines and CMEs were not supported by the scientific evidence at the time they were created, and they are not supported by the scientific evidence today. The Manufacturer Defendants and Related Unnamed Parties exerted control over these activities through their KOLs. The 2016 CDC Guideline recognizes that treatment guidelines can "change prescribing practices."

80. At all relevant times, the Manufacturer Defendants and Related Unnamed Parties controlled, funded, and acted in concert with these KOLs; they were legally responsible for the acts, omissions, and representations of these KOLs, who acted as their agents; and the Manufacturer Defendants and Related Unnamed Parties conspired with these KOLs regarding the conduct described herein.

81. Through all three of these avenues, the Manufacturer Defendants and Related Unnamed Parties disseminated false and deceptive statements about opioids.

### C. The Manufacturer Defendants and Related Unnamed Parties Intentionally Misled Doctors and Consumers About the Risks and Benefits of Opioids to Generate Billions of Dollars in Improper Profits.

82. As explained above, for decades doctors had viewed opioids with suspicion, judging that the risk of addiction made such drugs inappropriate in all but a small number of situations.

83. To convince doctors and patients in the United States that opioids can and should be used to treat chronic pain, the Manufacturer Defendants and Related Unnamed Parties had to

convince them that long-term opioid use is both safe and helpful. They did so by deceiving those doctors and patients about the risks and benefits of long-term opioid use, making claims that were not supported by or were contrary to the scientific evidence. Even though guidance from the FDA and the CDC based on that evidence confirm that their claims were false and misleading, the Manufacturer Defendants and Related Unnamed Parties have not corrected them and continue to spread them today.

1. The Manufacturer Defendants and Related Unnamed Parties Misrepresented the Known Risks of Long-Term Opioid Use.

84. The Manufacturer Defendants and Related Unnamed Parties deceptively trivialized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction, through a series of misrepresentations that have been conclusively debunked and rejected by the FDA and CDC. Specifically, they made false, misleading, and fraudulent representations to both physicians and consumers that: (1) starting patients on opioids was low-risk because most patients would not become addicted and those who were at greatest risk of addiction could be readily identified and managed; (2) patients who displayed signs of addiction probably were not addicted and, in any event, could easily be weaned from the drugs; (3) the use of higher opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, do not pose special risks; and (4) abuse-deterrent opioids both prevent abuse and overdose and are inherently less addictive. The Manufacturer Defendants and Related Unnamed Parties have not only failed to correct these misrepresentations, they continue to make them today.

*a. The Manufacturer Defendants and Related Unnamed Parties falsely represented that opioids pose a low risk of addiction.*

85. First, the Manufacturer Defendants and Related Unnamed Parties falsely minimized the risk of addiction and failed to disclose the greater risk of addiction with prolonged

use of opioids. Some illustrative examples of these false and misleading claims are described below:

- Mallinckrodt's former parent Company, Covidien, published a "patient resource," called "Opioid Safe Use and Handling Guide," which stated that: "Addiction does not often develop when taking opioid pain medicine as prescribed under the guidance of a health care provider, but it can occur;" and "Taking more than your prescribed amount of medication to treat your pain is not the same as addiction, but it can be very dangerous."[22] The guide further explains that opioid tolerance is different from addiction, by explaining that tolerance may cause a patient to take more opioids in order to receive pain relief.

- Actavis's predecessor caused a patient education brochure to be distributed in 2007 that claimed opioid addiction is possible, but "less likely if you have never had an addiction problem." Upon information and belief, based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis continued to use this brochure in 2009 and beyond.

- Purdue and Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which instructed that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative opioid prescriptions from multiple sources, or theft. This publication is still available online.

- Endo sponsored a website, Painknowledge.com, which claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." Another Endo website, PainAction.com, stated "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them."

- Endo distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated that: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem." A similar statement appeared on the Endo website www.opana.com.

- In another publication, Endo represented that "[i]n general, people who have no history of drug abuse, including tobacco, and use their opioid medication as directed will probably not become addicted."

- Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which described as "myth" the claim that opioids are addictive, and asserted as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain." This guide is still available online.

[22] CARES Alliance, "Opioid Safe Use and Handling Guide."

- Janssen currently runs a website, Prescriberesponsibly.com (last updated July 2, 2015), which claims that concerns about opioid addiction are "overestimated" and that that opioid addiction is unlikely unless the patient is recovering from past drug or alcohol abuse.

- Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*—which claims that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to "misconceptions about opioid addiction[]." This publication is still available online.

- In the APF publication *Getting the Help You Need*, the Manufacturer Defendants and Related Unnamed Parties represented that "[s]tudies and clinical practice have shown that the risk of addiction is small when [opioids] are appropriately prescribed and taken as directed."

- In the same APF publication, the Manufacturer Defendants and Related Unnamed Parties represented that "[u]nless you have a past or current history of substance abuse, the chance of addiction is low when these medications are prescribed properly and taken as directed."

- The same APF publication also stated: "Keep in mind, pain medicine in and of itself does not cause someone to become addicted."

- In a "Commonly Asked Questions and Answers" portion of the APF website, Manufacturer Defendants and Related Unnamed Parties represented that "addiction is very rare when pain medicines are properly prescribed and taken as directed."

- Cephalon sponsored a guidebook called *Opioid Medications and REMS: A Patient's Guide*, which falsely represented that "patients without a history of abuse or a family history of abuse do not commonly become addicted to opioids."

- Detailers for Purdue, Endo, and Janssen have minimized or omitted and continue to minimize or omit any discussion with doctors or their medical staff about the risk of addiction; misrepresented the potential for abuse of opioids with purportedly abuse-deterrent formulations; and routinely did not correct the misrepresentations noted above.

- APF's Executive Director represented that "when taken as prescribed, under the direction of a physician for pain relief, opioids are safe and effective, and only in rare cases lead to addiction." He further represented that "less than 1% of patients become addicted" to opioids.

86. One exemplar of these false claims were the statements made by pain-topics.org, a Mallinckrodt sponsored website that was active until at least June 2007 but which is now defunct, that proclaimed to be an organization "dedicated to offering contents that are evidence-

based, unbiased, non-commercial, and comply with the highest standards and principles of accrediting and other oversight organizations."[23]

87. The FAQ section of pain-topics.org contained misleading information about a concept called "pseudoaddiction," detailed further below. Pseudoaddiction is a concept invented to foster the misconception that signs of addiction, including shopping for doctors willing to newly write or refill prescriptions for opioids, or seeking early refills, actually reflected undertreated pain that should be addressed with more opioids—the medical equivalent of fighting fire by adding fuel. Specifically, the pain-topics.org website described pseudoaddiction as behavior that occurs in patients when pain is "undertreated" and includes patients becoming "very focused on obtaining opioid medications, and may be erroneously perceived as 'drug seeking."[24]

88. The website also characterized as "misinformation" the fact that patients who use opioids for long-term chronic pain become addicted, and questioned why the daily administration of medications such as insulin and antidepressants is not considered addiction when the daily administration of opioids is. In addition, the website stated that the constant media attention regarding opioid addiction, misuse and overdose creates a "false impression" that opioids should never be prescribed, and the number of "celebrities and street users" along with those who overdose from misuse is minimal in comparison to those who benefit from chronic opioid therapy.[25]

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[23]https://web.archive.org/web/20070701065905/http://www.pain-topics.org:80/contacts_aboutus/index.php

[24] https://web.archive.org/web/20071026152321/http://pain-topics.org/faqs/index1.php#tolerance (Last visited May 17, 2019.)

[25] *Id*.

89. Furthermore, pain-topics.org implied that if a patient is diagnosed with a pain condition and non-opioids fail to provide relief, that patient is "right" for opioids.[26] The website also said that the practice of not using opioids for long-term pain is "nonsensical."[27] It claimed that patients who do not legitimately need opioids "do not exhibit obvious causes of pain" or provide other information such as MRIs, medical records, or an event which caused the chronic pain."[28]

90. In addition, among its content, the website contained a handout titled Oxycodone Safety for Patients, which advised doctors that "[p]atients' fears of opioid addiction should be expelled."[29] The handout stated the following misleading information regarding the risk of addiction:

**Will you become dependent on or addicted to oxycodone?**

- After awhile, oxycodone causes *physical dependence*. That is, if you suddenly stop the medication you may experience uncomfortable withdrawal symptoms, such as diarrhea, body aches, weakness, restlessness, anxiety, loss of appetite, and other ill feelings. These may take several days to develop.
- This is not the same as *addiction*, a disease involving craving for the drug, loss of control over taking it or compulsive use, and using it despite harm. Addiction to oxycodone in persons without a recent history of alcohol or drug problems is rare.

This handout is still available to prescribers and patients today.

91. The FDA does not regulate unbranded advertising or marketing funneled through third-parties. Thus, neither the third-party unbranded materials, such as the information found on

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[26] *Id.*
[27] *Id.*
[28] *Id.*
[29] Lee A. Kral, *Commonsense Oxycodone Prescribing & Safety*, http://paincommunity.org/blog/wp-content/uploads/OxycodoneHandout.pdf.

pain-topics.org, nor the marketing messages or scripts relied on by Mallinckrodt's sales representatives, were reviewed or approved by the FDA.

92. Mallinckrodt's efforts to trivialize the risk of addiction were, and remain, at odds with the scientific evidence. Studies have shown that at least 8-12%, and as many as 30-40% of long-term users of opioids experience problems with addiction. In March 2016, the FDA emphasized the "known serious risk[] of . . . addiction"—"even at recommended doses"—of all opioids."[30] That same month, after a "systematic review of the best available evidence" by a panel excluding experts with conflicts of interest, the CDC published the CDC Guideline for prescribing opioids for chronic pain. The CDC Guideline noted that "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder" (a diagnostic term for addiction).[31] The CDC also emphasized that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."[32]

93. Mallinckrodt also claimed—without evidence—that long-term opioid use would help patients resume their lives and jobs. Mallinckrodt's website, in a section on "responsible use" of opioids, claimed that "[t]he effective pain management offered by medicines helps enable patients to stay in the workplace, enjoy interactions with family and friends, and remain an active member of society."[33]

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[30] *FDA announces safety labeling changes and postmarket study requirements for extended-release and long-acting opioid analgesics,* FDA (Sep. 10, 2013); *see also FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death,* FDA (Mar. 22, 2016), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm.

[31] CDC Guideline at 2.

[32] *Id.* at 21.

[33] Mallinckrodt Pharmaceuticals, Responsible Use, www.mallinckrodt.com/corporate-responsibility/responsible-use.

94. The Mallinckrodt sponsored pain-topics.org website also claimed that long-term use of opioids for treatment of chronic pain conditions would improve patients' function. The website stated that the benefits of using opioids for chronic pain include improvement to functions such as eating, sleeping, socializing, sexual activity, driving, walking and working. The website also claims that chronic opioid administration improves "quality of life."[34] The website further states that people who do not take opioids for long-term pain are "unable to participate in a normal family, vocational or other desired pursuits."[35]

95. Mallinckrodt's claims that long-term use of opioids improves patient function and quality of life are unsupported by clinical evidence. There are no controlled studies of the use of opioids beyond 12 weeks, and there is no evidence that opioids improve patients' pain and function long-term. On the contrary, the available evidence indicates opioids are not effective to treat chronic pain, and may worsen patients' health and pain. Increasing the duration of opioid use is strongly associated with an increasing prevalence of mental health conditions (depression, anxiety, post-traumatic stress disorder, and substance abuse), increased psychological distress, and greater health care utilization.

96. One pain specialist observed, "opioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally."[36] Studies of patients who suffer from chronic pain, for

[34] https://web.archive.org/web/20071025004137/http://pain-topics.org/pdf/OvercomingOpiophobia.pdf

[35] *Id*.

[36] Andrea Rubinstein, *Are We Making Pain Patients Worse?*, Sonoma Med. (Fall 2009), http://www.nbcms.org/about-us/sonoma-county-medical-association/magazine/sonoma-medicine-are-we-making-pain-patients-worse*?*

example, have consistently shown that patients experienced deteriorating function over time, as measured by ability to return to work, physical activity, pain relief, rates of depression, and subjective quality-of-life measures. Analyses of workers' compensation claims have found that workers who take opioids are almost four times more likely to reach costs over $100,000, stemming from greater side effects and slower returns to work. According to these studies, receiving an opioid for more than seven days also increased patients' risk of being on work disability one year later.

97. The FDA and other federal agencies have, for years, made clear the lack of evidence for claims that the use of opioids for chronic pain improves patients' function and quality of life.[37] The CDC Guideline concludes that "[w]hile benefits for pain relief, function and quality of life with long-term opioid use for chronic pain are uncertain, risks associated with long-term opioid use are clearer and significant."[38] According to the CDC, "for the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits [of opioids for chronic pain]."[39]

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[37] The FDA has warned other drug makers that claims of improved function and quality of life were misleading. *See,* Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), (rejecting claims that Actavis' opioid, Kadian, had an "overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."); Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Brian A. Markison, Chairman, President and Chief Executive Officer, King Pharmaceuticals, Inc. (March 24, 2008), (finding the claim that "patients who are treated with [Avinza (morphine sulfate ER)] experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."). The FDA's warning letters were available to Mallinckrodt on the FDA website.

[38] *Id* at 18.

[39] Thomas R. Frieden et al., *Reducing the Risks of Relief — The CDC Opioid-Prescribing Guideline*, 374 New Eng. J. Med. 1501-1504 (2016).

98. Each of the representations identified above—and other similar representations by the Manufacturer Defendants and Related Unnamed Parties—are false. Extensive medical research demonstrates that opioids pose a substantial risk of addiction, abuse, and overdose. In particular, opioids pose a substantial risk of addiction when they are used for extended periods of time—such as for treatment of chronic pain—and when they are administered outside the close supervision of medical professionals. Many studies have shown substantial risk of addiction where patients take opioids to treat chronic non-cancer pain.

99. Many patients become addicted to opioids even when they originally take opioids pursuant to a valid prescription. Indeed, one study found that 75% of those addicted to opioids first took them pursuant to a prescription. And research suggests that the overdose-death rate for those taking opioids pursuant to a prescription is higher than the rate for those using opioids non-medically.

100. One study examining opioid overdose deaths found that "92% of the decedents had been receiving [putatively] legitimate [opioid] prescriptions from health care providers for chronic pain."

101. Many patients become addicted to opioids even though they have no prior history of addiction or substance abuse. In fact, in 2016, the CDC "found insufficient evidence to determine how harms of opioids differ depending on past or current substance abuse disorder." Indeed, the 2016 CDC Guideline found that there is "extensive evidence" of the "possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction])." The Guideline points out that "[o]pioid pain medication use presents serious risks, including . . . opioid use disorder" and that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."

102. The FDA's announcement of changes to the labels for extended release ("ER") and long acting ("LA") opioids in 2013 and for immediate release ("IR") opioids in 2016 further exposed the falsity of the Manufacturer Defendants' and Related Unnamed Parties' claims about the low risk of addiction. In its announcements, the FDA found that "most opioid drugs have 'high potential for abuse'" and that opioids "are associated with a substantial risk of misuse, abuse, NOWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death." According to the FDA, because of the "known serious risks" associated with long-term opioid use, including "risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death," opioids should be used only "in patients for whom alternative treatment options" like non-opioid drugs have failed. The FDA further acknowledged that the risk is not limited to patients who seek drugs illicitly; addiction "can occur in patients appropriately prescribed" opioids.

103. The Manufacturer Defendants' and Related Unnamed Parties' own FDA-approved drug label warnings caution that opioids "expose[] users to risks of addiction, abuse and misuse, which can lead to overdose and death," that the drugs contain "a substance with a high potential for abuse," and that addiction "can occur in patients appropriately prescribed" opioids.

104. In a 2016 settlement agreement with Endo, the New York Attorney General found that opioid "use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical criteria for an opioid use disorder."

105. Until at least April 2012, Endo had claimed on its www.opana.com website that "[m]ost healthcare providers who treat patients with pain agree that patients treated with

prolonged opioid medicines usually do not become addicted," but the NY AG found that Endo had no evidence for that statement. Consistent with this, Endo agreed not to "make statements that . . . opioids generally are non-addictive" or "that most patients who take opioids do not become addicted" in New York. Endo has remained free, however, to make those statements throughout the rest of the nation.

106. Doctors, consumers, and insurers reasonably relied on these misrepresentations. As a result, many doctors prescribed opioids when they otherwise would not have, and many patients requested and obtained opioids when they otherwise would not have. Insurers kept Manufacturer Defendants' and Related Unnamed Parties' opioids in their formularies and paid more than they were worth.

107. In particular, the Manufacturer Defendants' and Related Unnamed Parties' misrepresentations induced both doctors and consumers to use opioids to treat chronic pain, and induced insurers not to question this practice, which widespread medical norms had viewed as inappropriate before their misinformation campaign.

108. The Manufacturer Defendants and Related Unnamed Parties knew that their representations described herein were false, and they made those representations with intent to defraud. The Manufacturer Defendants and Related Unnamed Parties intentionally made the representations described herein to United States citizens, residents, and businesses.

*b. The Manufacturer Defendants and Related Unnamed Parties falsely represented that many individuals who exhibit signs of addiction to opioids are experiencing "pseudoaddiction," which should be treated by increasing opioid use.*

109. Second, the Manufacturer Defendants and Related Unnamed Parties repeatedly misrepresented to insurers, doctors, and consumers that many individuals exhibiting signs of addiction were experiencing pseudoaddiction. This concept was originally put forward by J.

David Haddox, who later became a Vice President for Purdue, and popularized by Dr. Russell Portenoy, a KOL for Endo, Janssen, Cephalon, and Purdue. Manufacturer Defendants and Related Unnamed Parties further falsely represented that the proper treatment for "pseudoaddiction" is more opioids.

110. Examples of these deceptive claims include the following:

- Purdue and Cephalon sponsored *Responsible Opioid Prescribing* (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudoaddiction, rather than true addiction. Responsible Opioid Prescribing remains for sale online.

- Janssen sponsored, funded, and edited the Let's Talk Pain website, which in 2009 stated: "pseudoaddiction . . . refers to patient behaviors that may occur when pain is under-treated . . . . Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management." This website was accessible online until May 2012.

- Endo sponsored a National Initiative on Pain Control (NIPC) CME program in 2009 titled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*, which promoted pseudoaddiction by teaching that a patient's aberrant behavior was the result of untreated pain. Endo substantially controlled NIPC by funding NIPC projects; developing, specifying, and reviewing content; and distributing NIPC materials.

- Endo also represented that "[s]ometimes people behave as if they are addicted, when they are really in need of more medicine. This can be treated with higher doses of medicine."

- Purdue published a pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which described pseudoaddiction as a concept that "emerged in the literature" to describe the inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated."

- Purdue sponsored a CME program entitled *Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse* in 2011. In a role play, a chronic pain patient with a history of drug abuse tells his doctor that he is taking twice as many hydrocodone pills as directed. The narrator notes that because of pseudoaddiction, the doctor should not assume the patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or "overindulges in unapproved escalating doses." The doctor treats this patient by prescribing a high-dose, long-acting opioid.

- Detailers for Purdue have directed doctors and their medical staffs to PartnersAgainstPain.com, which contained false and misleading materials describing pseudoaddiction.

- Purdue and Cephalon sponsored *APF's Treatment Options: A Guide for People Living with Pain* (2007), which states: "Pseudo-addiction describes patient behaviors that may occur when pain is undertreated . . . Pseudo-addiction can be distinguished from true addiction in that this behavior ceases when pain is effectively treated."

111. These representations are false. Significant medical literature casts doubt on the concept of "pseudoaddiction." For example, one medical study reviewed all academic medical publications discussing "pseudoaddiction" and concluded that, "[o]f the 224 articles, none exist that attempted to empirically validate the concept of pseudoaddiction."

112. The same study found that many of the articles that considered "pseudoaddiction as a genuine clinical phenomenon" were funded by opioid producers, including Janssen and Purdue.

113. In addition, the CDC's opioid-prescribing guidelines do not recognize "pseudoaddiction" as a legitimate medical concept. The 2016 CDC Guideline does not recognize the concept of pseudoaddiction and nowhere recommends that opioid dosages be increased if a patient is not experiencing pain relief.

114. As Dr. Lynn Webster later recognized, the concept of pseudoaddiction "obviously became too much of an excuse to give patients more medication . . . . It led us down a path that caused harm. It is already something we are debunking as a concept."

115. Even Endo has effectively repudiated the concept of pseudoaddiction. In finding that "[t]he pseudoaddiction concept has never been empirically validated and in fact has been abandoned by some of its proponents," the NY AG, in its 2016 settlement with Endo, reported that "Endo's Vice President for Pharmacovigilance and Risk Management testified to [the NY AG] that he was not aware of any research validating the 'pseudoaddiction' concept" and

acknowledged the difficulty in distinguishing "between addiction and 'pseudoaddiction.'" Thus, Endo agreed not to "use the term 'pseudoaddiction' in any training or marketing" in New York.

116. Insurers, doctors and consumers reasonably relied on the Manufacturer Defendants' and Related Unnamed Parties' misrepresentations. As a result of that reasonable reliance, many doctors prescribed opioids when they otherwise would not have, and many patients requested and obtained opioids when they otherwise would not have. Insurers kept Manufacturer Defendants' and Related Unnamed Parties' opioids in their formularies and paid more than they were worth for them.

117. In particular, the false representations induced many doctors to increase opioid dosage based on the belief that patients' signs of addiction actually reflected "pseudoaddiction." In addition, the Manufacturer Defendants' and Related Unnamed Parties' false representations induced many doctors to continue prescribing opioids to patients exhibiting signs of addiction even though those doctors should have discontinued the prescriptions.

118. The Manufacturer Defendants and Related Unnamed Parties knew that their representations described herein were false and made those representations with intent to defraud. The Manufacturer Defendants and Related Unnamed Parties intentionally made their representations described herein to United States citizens, residents, and businesses.

*c. The Manufacturer Defendants and Related Unnamed Parties misrepresented the signs of addiction and the ease of preventing addiction.*

119. Third, the Manufacturer Defendants and Related Unnamed Parties repeatedly misrepresented the signs of addiction, the appropriate medical response to evidence of patient addiction or dependence, and the ease of preventing addiction. Specifically, they falsely instructed insurers, doctors, and patients that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow them reliably to identify and safely to prescribe

opioids to patients predisposed to addiction. The Manufacturer Defendants and Related Unnamed Parties targeted these misrepresentations at general practitioners and family doctors who often lack the time and expertise to closely manage higher-risk patients on opioids. These misrepresentations made these doctors feel more comfortable prescribing opioids to their patients, made patients more comfortable starting on opioid therapy for chronic pain, and induced insurers to not question this practice.

120. Examples of these deceptive claims include the following:

- Endo represented that "[t]aking opioids for pain relief is not addiction" and that "[a]ddiction to an opioid would mean that your pain has gone away but you still take the medicine regularly when you don't need it for pain, maybe just to escape from your problem."

- In the same publication, Endo suggested that patients use the following test to determine whether they are addicted to opioids: "Ask yourself: Would I want to take this medicine if my pain went away? If your answer no, you are taking opioids for the right reasons—to relieve pain and improve your function. You are not addicted."

- Endo paid for a 2007 supplement in the *Journal of Family Practice* written by a doctor who became a member of Endo's speakers bureau in 2010. The supplement, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids*, emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.

- Purdue sponsored a November 2011 webinar, *Managing Patient's Opioid Use: Balancing the Need and Risk*, which claimed that screening tools, urine tests, and patient agreements prevent "overuse of prescriptions" and "overdose deaths."

- As recently as 2015, Purdue has represented in scientific conferences that "bad apple" patients—and not opioids—are the source of the addiction crisis and that once those "bad apples" are identified, doctors can safely prescribe opioids without causing addiction.

- Detailers for Purdue have touted and continue to tout to doctors the reliability and effectiveness of screening or monitoring patients as a tool for managing opioid abuse and addiction.

121. These representations are false. In fact, a patient can be addicted to opioids while still experiencing pain. And a person addicted to opioids ordinarily is not in a position to judge objectively whether he or she would "want to take this medicine if [his or her] pain went away."

122. Moreover, the 2016 CDC Guideline confirms that these statements were false, misleading, and unsupported at the time they were made. The Guideline notes that there are no studies assessing the effectiveness of risk mitigation strategies—such as screening tools, patient contracts, urine drug testing, or pill counts widely believed by doctors to detect and deter abuse—"for improving outcomes related to overdose, addiction, abuse, or misuse." As a result, the Guideline recognizes that available risk screening tools "show insufficient accuracy for classification of patients as at low or high risk for [opioid] abuse or misuse" and counsels that doctors "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy."

123. The Manufacturer Defendants and Related Unnamed Parties intentionally made the representations described herein to United States citizens, residents, and businesses.

*d. The Manufacturer Defendants and Related Unnamed Parties falsely claimed that opioid dependence can easily be addressed by tapering and that opioid withdrawal is not a problem.*

124. Fourth, to minimize the risk and impact of addiction and to make doctors feel more comfortable starting patients on opioids, the Manufacturer Defendants and Related Unnamed Parties falsely claimed that opioid dependence can easily be addressed by tapering and that opioid withdrawal is not a problem, and failed to disclose the increased difficulty of stopping opioids after long-term use.

125. For example, a 2011 non-credit educational program sponsored by Endo, entitled *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms can be avoided by tapering a patient's opioid dose by 10%-20% for 10 days. Purdue sponsored APF's *A*

*Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation" without mentioning any hardships that might occur. This publication was available on APF's website until the organization dissolved in May 2012.

126. And detailers for Janssen have minimized the risk of addiction by telling doctors across the nation that their patients would not experience withdrawal if they tried to stop using opioids. The Manufacturer Defendants and Related Unnamed Parties deceptively minimized the significant symptoms of opioid withdrawal—which, as explained in the 2016 CDC Guideline, include drug craving, anxiety, insomnia, abdominal pain, vomiting, diarrhea, sweating, tremor, tachycardia (rapid heartbeat), spontaneous abortion and premature labor in pregnant women, and the unmasking of anxiety, depression, and addiction—and grossly understated the difficulty of tapering, particularly after long-term opioid use.

127. In fact, as the 2016 CDC Guideline recognizes, the duration of opioid use and the dosage of opioids prescribed should be "limit[ed]" to "minimize the need to taper opioids to prevent distressing or unpleasant withdrawal symptoms," because "physical dependence on opioids is an expected physiologic response in patients exposed to opioids for more than a few days." Moreover, "tapering opioids can be especially challenging after years on high dosages because of physical and psychological dependence" and there are difficulties associated with tapering, including the need to carefully identify "a taper slow enough to minimize symptoms and signs of opioid withdrawal" and to "pause[] and restart[]" tapers depending on the patient's response. The CDC also acknowledges the lack of any "high-quality studies comparing the effectiveness of different tapering protocols for use when opioid dosage is reduced or opioids are discontinued."

*e. The Manufacturer Defendants and Related Unnamed Parties falsely*

*claimed that doctors and patients could increase opioid dosages indefinitely without added risk.*

128. Fifth, the Manufacturer Defendants and Related Unnamed Parties falsely claimed that doctors and patients could increase opioid dosages indefinitely without added risk and failed to disclose the greater risks at higher dosages. The ability to escalate dosages was critical to the Manufacturer Defendants' and Related Unnamed Parties' efforts to market and sell opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients built up tolerance and lower dosages ceased to provide pain relief.

129. Examples of these deceptive claims include the following:

- Through its funding of the website pain-topics.org, Mallinckrodt claimed that there is no ceiling dosage for opioids, and that dosage should be determined by starting on low dosages and titrating up until a patient finds relief. The website does not disclose the dangers associated with higher doses, but claims that risks associated with opioids, such as death, overdoses and accidents, occur when patients do not take opioids as prescribed, or when the patient is taking other drugs or substances unknown to the prescribing doctor.

- Actavis's predecessor created a patient brochure for Kadian in 2007 that stated, "Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction." Upon information and belief, based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis continued to use these materials in 2009 and beyond.

- Purdue and Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which claims that some patients "need" a larger dose of an opioid, regardless of the dose currently prescribed. The guide stated that opioids have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. This guide is still available for sale online.

- Endo sponsored a website, painknowledge.com, which claimed in 2009 that opioid dosages may be increased until "you are on the right dose of medication for your pain."

- Endo distributed a pamphlet edited by a KOL entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*. In Q&A format, it asked "If I take the opioid now,

will it work later when I really need it?" The response is, "The dose can be increased. . . . You won't 'run out' of pain relief."

- Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which was distributed by its sales force. This guide listed dosage limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased opioid dosages.

- Through March 2015, Purdue's *In the Face of Pain* website promoted the notion that if a patient's doctor does not prescribe what, in the patient's view, is a sufficient dosage of opioids, he or she should find another doctor who will.

- Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that dosage escalations are "sometimes necessary," even unlimited ones, but did not disclose the risks from high opioid dosages. This publication is still available online.

- Purdue sponsored a CME entitled *Overview of Management Options* that is still available for CME credit. The CME was edited by a KOL and taught that non-steroidal anti-inflammatory drugs ("NSAIDs") and other drugs, but not opioids, are unsafe at high dosages.

- Purdue presented a 2015 paper at the College on the Problems of Drug Dependence challenging the correlation between opioid dosage and overdose.

130. These claims conflict with the scientific evidence, as confirmed by the FDA and CDC. The 2016 CDC Guideline states that the "[b]enefits of high-dose opioids for chronic pain are not established" while the "risks for serious harms related to opioid therapy increase at higher opioid dosage." More specifically, the CDC explains that "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages." The CDC also states that "there is an increased risk for opioid use disorder, respiratory depression, and death at higher dosages." That is why the CDC advises doctors to "avoid increasing dosages" above 90 morphine milligram equivalents per day.

131. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. Patients receiving high doses of opioids (e.g., doses greater than 100 mg morphine equivalent dose ("MED") per day) as part of long-term opioid therapy are approximately nine times more

likely to suffer overdose from opioid- related causes than those on low doses. As compared to available alternative pain remedies, scholars have suggested that tolerance to the respiratory depressive effects of opioids develops at a slower rate than tolerance to opioids' analgesic effects. Accordingly, the practice of continuously escalating doses to match pain tolerance can, in fact, lead to overdose even where opioids are taken as recommended.

132. In 2013, the FDA acknowledged "that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events." For example, the FDA noted that studies "appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality." In fact, a recent study found that 92% of persons who died from an opioid-related overdose were initially prescribed opioids for chronic pain.

*f. The Manufacturer Defendants and Related Unnamed Parties falsely claimed that the abuse-deterrent properties of some of their opioids can prevent and curb addiction and abuse.*

133. Finally, the Manufacturer Defendants' and Related Unnamed Parties' deceptive marketing of the so-called abuse-deterrent properties of some of their opioids has created false impressions that these opioids can prevent and curb addiction and abuse. Indeed, in a 2014 survey of 1,000 primary care physicians, nearly half reported that they believed abuse-deterrent formulations are inherently less addictive.

134. These abuse-deterrent formulations ("AD" opioids) are harder to crush, chew, or grind; become gelatinous when combined with a liquid, making them harder to inject; or contain a counteragent such as naloxone that is activated if the tablets are tampered with.

135. Despite this, AD opioids are not "impossible to abuse." They can be defeated, often quickly and easily. Moreover, they do not stop oral intake, the most common method of opioid misuse and abuse, and they do not reduce the rate of misuse and abuse by patients who

become addicted after using opioids long-term as prescribed or who escalate their use by taking more pills or higher doses.

136. As a result of these limitations on AD opioids and the heightened risk of misconceptions and the false belief that AD opioids can be prescribed safely, the FDA has cautioned that "[a]ny communications from the sponsor companies regarding AD properties must be truthful and not misleading (based on a product's labeling), and supported by sound science taking into consideration the totality of the data for the particular drug. Claims for AD opioid products that are false, misleading, and/or insufficiently proven do not serve the public health."

137. Despite this admonition, the Manufacturer Defendants and Related Unnamed Parties have made and continue to make misleading claims about the ability of their so-called abuse-deterrent opioid formulations to prevent or reduce abuse and addiction and the safety of these formulations.

138. For example, Mallinckrodt promoted both Exalgo (extended-release hydromorphone) and Xartemis XR (oxycodone and acetaminophen) as specifically formulated to reduce abuse. For example, Mallinckrodt's promotional materials stated that "the physical properties of EXALGO may make it difficult to extract the active ingredient using common forms of physical and chemical tampering, including chewing, crushing and dissolving."[40] One member of the FDA's Controlled Substance Staff, however, noted in 2010 that hydromorphone has "a high

[40] Mallinckrodt Press Release, *FDA Approves Mallinckrodt's EXALGO® (hydromorphone HCl) Extended-Release Tablets 32 mg (CII) for Opioid-Tolerant Patients with Moderate-to-Severe Chronic Pain* (Aug. 27, 2012), available at http://newsroom.medtronic.com/phoenix.zhtml?c=251324&p=irol-newsArticle&ID=2004159

abuse potential comparable to oxycodone" and further stated that "we predict that Exalgo will have high levels of abuse and diversion."[41]

139. In addition, with respect to Xartemis XR, Mallinckrodt's promotional materials stated that "XARTEMIS XR has technology that requires abusers to exert additional effort to extract the active ingredient from the large quantity of inactive and deterrent ingredients."[42] In anticipation of Xartemis XR's approval, Mallinckrodt added 150-200 sales representatives to promote it, and CEO Mark Trudeau said the drug could generate "hundreds of millions in revenue."[43]

140. The CDC Guideline confirms that "[n]o studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," noting that the technologies "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by non-oral routes."[44] Tom Frieden, the Director of the CDC, reported that his staff could not find "any evidence showing the updated opioids [abuse deterrent opioids] actually reduce rates of addiction, overdoses, or death."[45]

141. Mallinckrodt promotes patented technology as the solution to opioid abuse and addiction, but none of its "technology" addresses oral ingestion, and its statements regarding abuse-deterrent formulations give the misleading impression that doctors need not worry about the

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[41] http://www.fda.gov/downloads/advisorycommittees/committeesmeetingmaterials/drugs/anestheticandanalgesicdrugproductsadvisorycommittee/ucm187490.pdf at 157-58.

[42] Mallinckrodt, *Responsible Use of Opioid Pain Medications* (Mar. 7, 2014) at 14.

[43] Samantha Liss, *Mallinckrodt banks on new painkillers for sales*, St. Louis Business Journal (Dec. 30, 2013), available at http://argentcapital.com/mallinckrodt-banks-on-new- painkillers-for-sales

[44] CDC Guideline at 22.

[45] Matthew Perrone, Drugmakers Push Profitable, but Unproven, Opioid Solution, Assoc. Press (Jan. 2, 2017), available at http://www.detroitnews.com/story/news/nation/2017/01/02/painkillers-drugmakers-addictive/96095558.

abuse of these opioids. The above representations and resulting implications that Exalgo and Xartemis XR would prevent abuse and were, therefore, safer than other opioids were false and misleading.

142. Likewise, Endo has marketed Opana ER as tamper- or crush-resistant and less prone to misuse and abuse even though: (1) the FDA rejected Endo's petition to approve Opana ER as abuse-deterrent in 2012; (2) the FDA warned in a 2013 letter that there was no evidence that Opana ER "would provide a reduction in oral, intranasal or intravenous abuse"; and (3) Endo's *own* studies, which it failed to disclose, showed that Opana ER could still be ground and chewed. Endo's advertisements for the 2012 reformulation of Opana ER misleadingly claimed that it was designed to be crush resistant, suggesting it was more difficult to abuse. And since 2012, detailers for Endo have informed doctors that Opana ER is harder to abuse, and nurse practitioners have reported receiving tamper- and crush-resistant messages regarding Opana ER and demonstrations of Opana ER's purportedly abuse-deterrent properties.

143. In its 2016 settlement with the NY AG, Endo agreed not to make statements in New York that Opana ER was "designed to be, or is crush resistant." The NY AG found those statements false and misleading because there was no difference in the ability to extract the narcotic from Opana ER. The NY AG also found that Endo failed to disclose its own knowledge of the crushability of redesigned Opana ER in its marketing to formulary committees and pharmacy benefit managers.

144. Because Opana ER could be "readily prepared for injection" and was linked to outbreaks of HIV and a serious blood disease, in May 2017, an FDA advisory committee recommended that Opana ER be withdrawn from the market. The FDA adopted this recommendation on June 8, 2017 and requested that Endo withdraw Opana ER from the market.

145. As another example, Purdue has engaged in deceptive marketing of its AD opioids—*i.e.*, reformulated Oxycontin and Hysingla. Before April 2013, Purdue did not market its opioids based on their abuse-deterrent properties. However, prescribers report that, beginning in 2013, detailers from Purdue regularly touted the so-called abuse-deterrent properties of Purdue's opioid products as a selling point to differentiate those products from their competitors. Specifically, these detailers: (1) claim that Purdue's AD opioids prevent tampering and cannot be crushed or snorted; (2) claim that Purdue's AD opioids prevent or reduce opioid misuse, abuse, and diversion; are less likely to yield a euphoric high; and are disfavored by opioid abusers; (3) claim that Purdue's AD opioids are "safer" than other opioids; and (4) fail to disclose that Purdue's AD opioids do not impact oral misuse and that its abuse-deterrent properties can be defeated.

146. These statements and omissions by Purdue are false and misleading and conflict with or are inconsistent with the FDA-approved label for Purdue's AD opioids—which indicates that abusers do seek them because they can be snorted, that their abuse-deterrent properties can be defeated, and that they can be abused orally notwithstanding their abuse-deterrent properties.

147. Testimony in litigation against Purdue and other evidence indicates that Purdue knew and should have known that "reformulated OxyContin is not better at tamper resistance than the original OxyContin" and is still regularly tampered with and abused. Websites and message boards used by drug abusers, such as bluelight.org and Reddit, also report a variety of ways to tamper with OxyContin and Hysingla, including through grinding, microwaving then freezing, or drinking soda or fruit juice in which the tablet has been dissolved. Even Purdue's own website describes a study it conducted that found continued abuse of OxyContin with so-

called abuse-deterrent properties. Finally, there are no studies indicating that Purdue's AD opioids are safer than any other opioid products.

148. A 2015 study also shows that many opioid addicts are abusing Purdue's AD opioids through oral intake or by defeating the abuse-deterrent mechanism. Indeed, one-third of the patients in the study defeated the abuse-deterrent mechanism and were able to continue inhaling or injecting the drug. And to the extent that the abuse of Purdue's AD opioids was reduced, those addicts simply shifted to other drugs such as heroin.

149. In spite of all this, J. David Haddox, the Vice President of Health Policy for Purdue, falsely claimed in 2016 that the evidence does not show that Purdue's AD opioids are being abused in large numbers.

150. The 2016 CDC Guideline states that "[n]o studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," noting that the technologies "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by nonoral routes." Tom Frieden, the Director of the CDC, has further reported that his staff could not find "any evidence showing the updated opioids [abuse deterrents] actually reduce rates of addiction, overdoses, or death."

151. These false and misleading claims about the abuse-deterrent properties of the Manufacturer Defendants' and Related Unnamed Parties' opioids are especially troubling. First, the Manufacturer Defendants and Related Unnamed Parties are using these claims in a spurious attempt to rehabilitate their image as responsible opioid manufacturers. Indeed, several prescribers have reported that Purdue has conveyed that its sale of AD opioids is "atonement" for its earlier sins even though its true motive was to preserve the profits it would have lost when its patent for OxyContin expired. Indeed, Purdue introduced its first AD opioid days before that

patent would have expired and petitioned the FDA to withdraw its non-AD opioid as unsafe in an effort to prevent generic competition. Second, these claims have falsely assuaged doctors' concerns about the toll caused by the explosion in opioid prescriptions and use and encouraged doctors to prescribe AD opioids under the mistaken belief that these opioids are safer, even though they are not. Finally, these claims are causing doctors to prescribe more AD opioids, which are far more expensive than other opioid products even though they provide little or no additional benefit.

152. These numerous, longstanding misrepresentations of the risks of long-term opioid use spread by the Manufacturer Defendants and Related Unnamed Parties successfully convinced doctors and patients to discount those risks, and convinced insurers to continue paying, and overpaying, for AD formulations.

2. The Manufacturer Defendants and Related Unnamed Parties Falsely Overstated the Positive Long-Term Outcomes of Opioids in Cases of Chronic Pain.

153. A doctor's decision to prescribe any treatment—including opioids—always depends on the balancing of the risks posed by the treatment against the likely benefits from the treatment. As described above, the Manufacturer Defendants and Related Unnamed Parties repeatedly misrepresented the risks associated with opioids to persuade insurers, doctors, and consumers that opioids pose only minor risks that can be easily screened for, recognized, and avoided.

154. The Manufacturer Defendants and Related Unnamed Parties also misrepresented the other side of the balance, falsely asserting that opioids produce positive long-term outcomes in cases of chronic pain.

155. As the 2016 CDC Guideline makes clear, there is "insufficient evidence to determine the long-term benefits of opioid therapy for chronic pain." In fact, the CDC found that

"[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤ 6 weeks in duration)" and that other treatments were more or equally beneficial and less harmful than long-term opioid use. The FDA also has recognized the lack of evidence to support long-term opioid use. In 2013, the FDA stated that it was "not aware of adequate and well-controlled studies of opioids use longer than 12 weeks." Despite this, the Manufacturer Defendants and Related Unnamed Parties falsely and misleadingly touted the benefits of long-term opioid use, which they suggested were supported by scientific evidence.

156. For example, the Manufacturer Defendants and Related Unnamed Parties falsely claimed that long-term opioid use improved patients' function and quality of life. Examples of these deceptive claims include the following:

- Actavis distributed an advertisement that claimed that the use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on [their] body and [their] mental health," and help patients enjoy their lives.

- Endo distributed advertisements that claimed that the use of Opana ER for chronic pain would allow patients to perform demanding tasks, like construction work or work as a chef, and portrayed seemingly healthy, unimpaired subjects.

- Janssen sponsored and edited a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which states as "a fact" that "opioids may make it easier for people to live normally." The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs and states that "[u]sed properly, opioid medications can make it possible for people with chronic pain to 'return to normal.'"

- Purdue ran a series of advertisements for OxyContin in 2012 in medical journals entitled "Pain vignettes," which were case studies featuring patients with pain conditions persisting over several months and recommending OxyContin for them. The ads implied that OxyContin improves patients' function.

- *Responsible Opioid Prescribing* (2007), sponsored and distributed by Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients' function. The book remains for sale online.

- Purdue and Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids "give [pain patients] a quality of life [they] deserve." The guide was available online until APF shut its doors in May 2012.

- Endo's NIPC website painknowledge.com claimed in 2009 that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make misleading claims about function, and Endo closely tracked visits to the site.

- Endo was the sole sponsor, through NIPC, of a series of non-credit educational programs titled *Persistent Pain in the Older Patient*, which claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning." The CME was disseminated via webcast.

- Janssen sponsored, funded, and edited a website, *Let's Talk Pain*, in 2009, which featured an interview edited by Janssen claiming that opioids allowed a patient to "continue to function." This video is still available today on YouTube.

- Purdue sponsored the development and distribution of APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "multiple clinical studies" have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients." The Policymaker's Guide was originally published in 2011 and is still available online today.

- In a 2015 video on Forbes.com discussing the introduction of Hysingla ER, Purdue's Vice President of Health Policy, J. David Haddox, talked about the importance of opioids, including Purdue's opioids, to chronic pain patients' "quality of life," and complained that CDC statistics do not take into account that patients could be driven to suicide without pain relief.

- Since at least May 21, 2011, Purdue's, Endo's, and Janssen's sales representatives have conveyed to prescribers the message that opioids will improve patient function.

157. The scientific literature does not support these claims. The FDA and other federal agencies have made this clear for years. For example, the 2016 CDC Guideline concluded that "there is no good evidence that opioids improve pain or function with long-term use, and . . . complete relief of pain is unlikely." In addition, the CDC stated that "[n]o evidence shows a

long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later . . . ." "Although opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy." "[E]vidence is limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia."

158. The CDC also noted that the risks of addiction and death "can cause distress and inability to fulfill major role obligations." As a matter of common sense (and medical evidence), drugs that can kill patients or commit them to a life of addiction or recovery do not improve their function and quality of life.

159. The 2016 CDC Guideline was not the first time a federal agency repudiated Manufacturer Defendants' and Related Unnamed Parties' claim that opioids improved function and quality of life. In 2010, the FDA warned Actavis, in response to its advertising, that "[w]e are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience . . . results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."

160. In 2008, the FDA sent a warning letter to an opioid manufacturer, making clear "that [the claim that] patients who are treated with the drug experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."

161. In addition, Purdue has misleadingly promoted OxyContin as being unique among opioids in providing 12 continuous hours of pain relief with one dose. In fact, OxyContin does not last for 12 hours—a fact that Purdue has known at all times relevant to this action. According to Purdue's own research, OxyContin wears off in under six hours in one quarter of patients and in under 10 hours in more than half. This is because OxyContin tablets release approximately 40% of their active medicine immediately, after which release tapers. This triggers a powerful initial response, but provides little or no pain relief at the end of the dosing period, when less medicine is released. This phenomenon is known as "end of dose" failure, and the FDA found in 2008 that a "substantial number" of chronic pain patients taking OxyContin experience it. This not only renders Purdue's promise of 12 hours of relief false and misleading, it also makes OxyContin more dangerous because the declining pain relief patients experience toward the end of each dosing period drives them to take more OxyContin before the next dosing period begins, quickly increasing the amount of the drug they are taking and spurring growing dependence.

162. Purdue's competitors were aware of this problem. For example, Endo ran advertisements for Opana ER referring to "real" 12-hour dosing. Nevertheless, Purdue falsely promoted OxyContin as if it were effective for a full 12 hours. Indeed, Purdue's sales representatives were instructed to tell doctors that OxyContin lasts a full 12 hours. And if a doctor suggested that OxyContin does not last 12 hours, these sales representatives, at Purdue's instruction, recommended increasing the dose, rather than the frequency of use. Purdue gave its sales representatives these instructions to prevent doctors from switching to a different drug and to address the unwillingness of insurers to pay for more frequent use of OxyContin.

163. The Manufacturer Defendants' and Related Unnamed Parties' branded ads also deceptively portrayed the benefits of opioids for chronic pain. For example, Endo has distributed and made available on its website opana.com a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like construction worker and chef, misleadingly implying that the drug would provide long-term pain relief and functional improvement. Purdue also ran a series of ads, called "Pain vignettes," for OxyContin in 2012 in medical journals. These ads featured chronic pain patients and recommended OxyContin for each. One ad described a "54-year-old writer with osteoarthritis of the hands" and implied that OxyContin would help the writer work more effectively. Endo and Purdue agreed in late 2015 and 2016 to halt these misleading representations in New York, but they may continue to disseminate them other parts of the country.

164. The Manufacturer Defendants and Related Unnamed Parties also repeatedly made these representations in writing. For example, in the APF publication *Exit Wounds*, Manufacturer Defendants and Related Unnamed Parties described opioids as "the 'gold standard' of pain medications" and claimed that, if taken properly, opioids "increase a person's level of functioning."

165. These representations are false. Medical research does not support the conclusion that opioids increase positive long-term outcomes in cases of chronic pain.

166. The Manufacturer Defendants and Related Unnamed Parties knew that the representations described above were false, and they made those representations with intent to defraud. The Manufacturer Defendants and Related Unnamed Parties intentionally made the representations described herein to United States citizens, residents, and businesses.

3. <u>The Manufacturer Defendants and Related Unnamed Parties Falsely Represented the Relative Risks Associated with Non-Opioid Pain-Relief and Pain-Treatment Strategies.</u>

167. In addition to their misrepresentations regarding opioids, the Manufacturer Defendants and Related Unnamed Parties also falsely and misleadingly emphasized or exaggerated the risks of competing products like NSAIDs, so that doctors and patients would favor opioids for treatment of chronic pain.

168. For example, the Manufacturer Defendants and Related Unnamed Parties overstated the number of deaths from NSAIDs and prominently featured the risks of NSAIDs, while minimizing or failing to mention the serious risks of opioids. Once again, these misrepresentations contravene pronouncements and guidance from the FDA and CDC based on the scientific evidence. Indeed, the FDA changed the labels for ER/LA opioids in 2013 and IR opioids in 2016 to state that opioids should only be used as a last resort "in patients for which alternative treatment options" like non-opioid drugs "are inadequate." And the 2016 CDC Guideline states that NSAIDs, not opioids, should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.

169. The CDC has emphasized that non-opioid therapies are the "preferred" approach for treating chronic pain. Non-drug alternative treatments for chronic pain include a variety of treatments, including but not limited to cognitive behavioral therapy; exercise therapy; changes in diet or nutrition; and chiropractic and massage treatment. In addition, pharmaceutical alternatives to opioids include over-the-counter analgesics; NSAIDs; non-opioid prescription analgesics; and other drugs. The CDC has concluded that extensive research shows that these non-opioid treatment options offer greater benefits than long-term opioid treatment for chronic pain.

170. The Manufacturer Defendants and Related Unnamed Parties recognized that the availability of these alternatives would reduce the demand for their opioid products. To reduce

the comparative demand for these alternatives to opioids, the Manufacturer Defendants and Related Unnamed Parties misrepresented both the risks and benefits associated with many alternative treatment options.

171. The Manufacturer Defendants and Related Unnamed Parties repeatedly made these representations in writing. For example, in the APF publication *Exit Wounds*, the Manufacturer Defendants and Related Unnamed Parties represented that if NSAIDs are taken in high doses, they can have "life threatening" effects. But the Manufacturer Defendants and Related Unnamed Parties intentionally omitted the material fact that opioids pose severe risks—including significant risks of overdose and death—at high doses. In the same publication, the Manufacturer Defendants and Related Unnamed Parties represented that acetaminophen poses significant health risks in large doses, but they intentionally omitted the material fact that opioids also pose severe risks at high doses.

172. In the APF publication *Treatment Options: A Guide for People Living with Pain*, the Manufacturer Defendants and Related Unnamed Parties represented that "NSAIDs can cause life-threatening side effects in some persons" and that "[t]here are 10,000 to 20,000 deaths each year because of the side effects of this class of medicines." But the Manufacturer Defendants and Related Unnamed Parties intentionally omitted the material fact that opioids similarly pose severe and life-threatening effects and that comparable numbers of people die each year from opioid use. Indeed, one study found that since 1999, approximately 183,000 people died in the United States from opioid-related overdoses—that is, a little more than 10,000 per year.

173. In these and other similar representations, the Manufacturer Defendants and Related Unnamed Parties repeatedly emphasized the risks associated with alternative pain treatments without disclosing similar—and often much more severe—risks associated with

opioids. In reality, opioids pose more severe risks than do nearly all other pain-treatment options. One study found that the risk of death from out-of-hospital use of opioids was almost twice as likely to result in death than the use of alternatives like analgesic anticonvulsants.

174. These intentional omissions rendered the Manufacturer Defendants' and Related Unnamed Parties' representations false, misleading, deceptive, and fraudulent. Both doctors and consumers reasonably relied on these misrepresentations. And as a result of that reasonable reliance, many doctors prescribed opioids when they otherwise would not have, many patients requested and obtained opioids when they otherwise would not have, and insurers continued to pay for opioids when they would not have.

175. In particular, the Manufacturer Defendants' and Related Unnamed Parties' misrepresentations led many doctors to prescribe opioids when they otherwise would have prescribed or recommended non-opioid alternative treatments, and insurers covered opioids when they would have established policies that favored other pain treatment. And their misrepresentations led many consumers to request and/or take opioids when they otherwise would have requested and/or taken non-opioid alternatives.

176. The Manufacturer Defendants and Related Unnamed Parties knew that the representations described herein were false, and they made those representations with intent to defraud. The Manufacturer Defendants and Related Unnamed Parties intentionally made the representations described herein to United States citizens, residents, and businesses.

### D. The Manufacturer Defendants and Related Unnamed Parties Engaged in Other Unlawful and Unfair Misconduct.

177. In addition to the misrepresentations described above, the Manufacturer Defendants and Related Unnamed Parties engaged in other misconduct, including failing to

recognize or to act on knowledge that their opioids were being diverted, and targeting susceptible prescribers and vulnerable patient populations.

1. The Manufacturer Defendants and Related Unnamed Parties Failed to Act on Their Knowledge of the Diversion of Their Opioid Drugs.

178. The Manufacturer Defendants and Related Unnamed Parties are able to track the distribution and prescription of their opioids, but failed to act on suspicious prescriptions. To the contrary, they continued to market and provide incentives for doctors to prescribe their opioids.

179. For example, until at least 2007, Defendant Mallinckrodt deceptively promoted opioids through the website it funded, pain-topics.org. From 2008 until present, Mallinckrodt then compounded this harm by failing to put in place appropriate procedures to ensure suspicious orders would be reported and instead, continuing to fill orders which supplied far more opioids than were justified. Each of Mallinckrodt's shipments of opioids into the stream of commerce were fulfilled without an adequate system in place to investigate, report, and refuse to fill orders that they knew or should have known were suspicious, violated both its common law duties and statutory duties across the nation.

180. Under the common law applicable in every part of the nation, Mallinckrodt had a duty to exercise reasonable care in selling dangerous narcotic substances. Any time Mallinckrodt filled and failed to report orders that it knew or should have known were likely being diverted for illicit uses, Mallinckrodt breached that duty and created and failed to prevent a foreseeable risk of harm to United States residents. In addition, Mallinckrodt had a duty, when speaking publicly about opioids and its efforts to combat diversion, to speak accurately and truthfully.

181. Mallinckrodt has several responsibilities with respect to suspicious orders of opioids. First, it must set up a system designed to detect such orders. That would include

reviewing its own data, relying on its observations of prescribers and pharmacies, and following up on reports or concerns of potential diversion. Second, it must refuse to fill suspicious orders and only fill orders flagged as potentially suspicious if, after conducting due diligence, it can determine that the order is not likelyto be diverted into illegal channels. And, third, all suspicious orders must be reported to relevant enforcement authorities.

182. The purpose of the reporting rules is to create a "closed" system intended to reduce the diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control.[46]

183. Mallinckrodt was well aware it had an important role to play in this system, and also knew or should have known that its failure to comply with its reporting obligations would have serious consequences.

184. In a letter to registrants, including Mallinckrodt, on December 27, 2007, the DEA reminded Mallinckrodt that, as a registered manufacturer of controlled substances, it shares, and must abide by, statutory and regulatory duties to "maintain effective controls against diversion" and "design and operate a system to disclose to the registrant suspicious orders of controlled substances."[47] The DEA's December 27, 2007 letter reiterated the obligation to detect, report, and not fill suspicious orders and provided detailed guidance on what constitutes a suspicious order and how to report (e.g., by specifically identifying an order as suspicious, not merely transmitting data to the DEA). Finally, the letter references the Revocation of Registration

[46] *See* 1970 U.S.C.C.A.N. 4566, 4571-72.

[47] *See* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Dec. 27, 2007), filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14- 8.

issued in *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487-01 (July 3, 2007), which discusses the obligation to report suspicious orders and "some criteria to use when determining whether an order is suspicious."[48]

185. In 2011, the DEA began to investigate Mallinckrodt after DEA investigators noted large amounts of Mallinckrodt's oxycodone being sent to Florida. The investigation resulted in a fine of $35 million for Mallinckrodt's failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements. The Department of Justice and DEA determined that Mallinckrodt ignored its responsibility to report suspicious orders of as many as 500 million of its pills that were sent to Florida from 2008 to 2012, which was 66% of all oxycodone sold in the state. According to the Washington Post, an internal summary of the federal case against Mallinckrodt found that "Mallinckrodt's response was that 'everyone knew what was going on in Florida but they had no duty to report it.'"[49]

186. In the press release accompanying the settlement, the Department of Justice stated that Mallinckrodt "did not meet its obligations to detect and notify DEA of suspicious orders of controlled substances such as oxycodone, the abuse of which is part of the current opioid epidemic. These suspicious order monitoring requirements exist to prevent excessive sales of controlled substances, like oxycodone . . . . Mallinckrodt's actions and omissions formed a link in the chain of supply that resulted in millions of oxycodone pills being sold on the street. . . .

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[48] *See* 2007 Rannazzisi Letter.

[49] *The Government's Struggle to Hold Opioid Manufacturers Accountable:Sixty-Six Percent of All Oxycodone Sold in Florida Came From This Company. But the DEA's Case Against It Faltered*, Wash. Post, (Apr. 2, 2017), https://www.washingtonpost.com/graphics/investigations/dea-mallinckrodt/?utm_term=.256b39de1578.

'Manufacturers and distributors have a crucial responsibility to ensure that controlled substances do not get into the wrong hands' . . ."[50]

187. Among the allegations resolved by the settlement, the government alleged "Mallinckrodt failed to design and implement an effective system to detect and report 'suspicious orders' for controlled substances—orders that are unusual in their frequency, size, or other patterns . . . [and] Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders."[51]

188. The 2017 Mallinckrodt MOA further details the DEA's allegations regarding Mallinckrodt's failures to fulfill its legal duties as an opioid manufacturer:

> With respect to its distribution of oxycodone and hydrocodone products, Mallinckrodt's alleged failure to distribute these controlled substances in a manner authorized by its registration and Mallinckrodt's alleged failure to operate an effective suspicious order monitoring system and to report suspicious orders to the DEA when discovered as required by and in violation of 21 C.F.R. § 1301.74(b). The above includes, but is not limited to Mallinckrodt's alleged failure to:
>
> i. conduct adequate due diligence of its customers;
>
> ii. detect and report to the DEA orders of unusual size and frequency;
>
> iii. detect and report to the DEA orders deviating substantially from

[50] *See* Press Release, *U.S. Dep't of Justice, Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations* (July 11, 2017), https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders.

[51] *Id.*

normal patterns including, but not limited to, those identified in letters from the DEA Deputy Assistant Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007:

1. orders that resulted in a disproportionate amount of a substance which is most often abused going to a particular geographic region where there was known diversion,
2. orders that purchased a disproportionate amount of a substance which is most often abused compared to other products, and
3. orders from downstream customers to distributors who were purchasing from multiple different distributors, of which Mallinckrodt was aware;

iv. use "chargeback" information from its distributors to evaluate suspicious orders. Chargebacks include downstream purchasing information tied to certain discounts, providing Mallinckrodt with data on buying patterns for Mallinckrodt products; and

v. take sufficient action to prevent recurrence of diversion by downstream customers after receiving concrete information of diversion of Mallinckrodt product by those downstream

customers.[52]

189. In connection with the settlement, Mallinckrodt admitted that "[a]s a registrant under the CSA, Mallinckrodt had a responsibility to maintain effective controls against diversion, including a requirement that it review and monitor these sales and report suspicious orders to DEA."[53] Mallinckrodt further stated that it "recognizes the importance of the prevention of diversion of the controlled substances they manufacture" and agreed that it would "design and operate a system that meets the requirements of 21 CFR 1301.74(b) . . . [such that it would] utilize all available transaction information to identify suspicious orders of any Mallinckrodt product."[54] Mallinckrodt specifically agreed "to notify DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt controlled substances that Mallinckrodt discovers."[55]

190. Mallinckrodt also acknowledged that at certain times prior to January 1, 2012, certain aspects of its "system to monitor and detect suspicious orders did not meet the standards outlined in letters from the DEA Deputy Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007."[56]

191. Mallinckrodt, through its internal sources, knew or should have known that some of the millions of pills it ignored its responsibility to report were being used to fill suspicious orders in Florida, and knew or should have known that those opioids were being diverted to other

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[52] Administrative Memorandum of Agreement between the United States Department of Justice, the Drug Enforcement Agency, and Mallinckrodt, plc. and its subsidiary Mallinckrodt, LLC (July 10, 2017), https://www.justice.gov/usao-edmi/press-release/file/986026/download. ("2017 Mallinckrodt MOA"), at 2-3.

[53] *Id.* at 1.

[54] *Id.* at 4.

[55] *Id.*

[56] *Id.*

states. DOJ prosecutors found that Mallinckrodt knew of DEA enforcement actions against distributors for failing to report the disproportionately large amounts of painkillers they were shipping to retail customers in Florida and other states. Moreover, Mallinckrodt recognized in November 2010 that 68% of the purchases by one of its distributors, Cincinnati-based KeySource Medical, Inc., were for prescription opioids, and that 91% of this customer's purchasers were sent to Florida.[57]

192. Mallinckrodt also had other information that would have alerted it to potential diversion. Mallinckrodt acknowledged that "[a]s part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their direct customers (distributors). The transaction information contains data relating to the direct customer sales of controlled substances to 'downstream' registrants." As part of the settlement, Mallinckrodt agreed that, from this data, it could and would "report to the DEA when Mallinckrodt concludes that the chargeback data or other information indicates that a downstream registrant poses a risk of diversion."[58] While the 2017 settlement arose out of Mallinckrodt's failure to report suspicious orders in Florida, upon information and belief, it is indicative of a systemic failure that continues to this day, not only in Florida, but across the country.

193. Mallinckrodt claims on its website to be "committed both to helping health care providers treat patients in pain and to fighting opioid misuse and abuse," and further asserts that: "In key areas, our initiatives go beyond what is required by law. We address diversion and abuse

[57] United States' Opposition to Plaintiff's Motion for a Preliminary Injunction, *KeySource Medical Inc. v. Holder*, No. 1:11-cv-00393, Doc. 9 at 6 (S.D. Ohio June 30, 2011).
[58] *Id*.

through a multidimensional approach that includes educational efforts, monitoring for suspicious orders of controlled substances . . .”[59]

194. These public statements created the false and misleading impression that Mallinckrodt has rigorously carried out its duty to report suspicious orders and to exercise due diligence to prevent diversion of these dangerous drugs, and also worked voluntarily to prevent diversion as a matter of corporate responsibility. The truth, of course, is that Mallinckrodt failed to put in place appropriate procedures to ensure suspicious orders would be reported and instead, continued to fill suspicious orders, which supplied far more opioids than were justified and led to diversion of opioids across the nation. Furthermore, far from trying to address diversion, Mallinckrodt worked to defeat programs and laws designed to prevent diversion through its sponsorship of APA and USPF.

195. Purdue, too, through its sales representatives, pressed doctors to prescribe its opioids in order to be rewarded with talks paid by Purdue. One doctor reported that a Purdue sales representative told her that she would no longer be asked to give paid talks unless she increased her prescribing of Purdue’s drugs. Another doctor confirmed that, while on Purdue’s speakers’ bureau, he was not asked to give many paid talks because he did not commonly prescribe Butrans, and doctors do not “get talks” if they do not prescribe the drug.

196. Although the DEA has repeatedly informed Purdue about its legal “obligation to design and operate a system to disclose . . . suspicious orders of controlled substances” and to inform the DEA “of suspicious orders when discovered,” Purdue unlawfully and unfairly failed

[59] Mallinckrodt website, Our Programs, http://www2.mallinckrodt.com/Responsibility/Responsible_Use/Our_Programs/

to report or address illicit and unlawful prescribing of its drugs, despite knowing about it for years. *See* 21 C.F.R. § 1301.74(b); 21 U.S.C. § 823(e).

197. For more than a decade, Purdue has been able to track the distribution and prescribing of its opioids down to the retail and prescriber levels. Through its extensive network of sales representatives, Purdue had knowledge of the prescribing practices of tens, if not hundreds of thousands of doctors and could identify doctors who displayed red flags for diversion such as those whose waiting rooms were overcrowded, whose parking lots had numerous out-of-state vehicles, and whose patients seemed young and healthy or homeless. Using this information, Purdue has maintained a database since 2002 of doctors suspected of inappropriately prescribing its drugs. Rather than report these doctors to state medical boards or law enforcement authorities (as Purdue is legally obligated to do) or cease marketing to them, Purdue used the list to demonstrate the high rate of diversion of OxyContin—the same OxyContin that Purdue had promoted as less addictive—in order to persuade the FDA to bar the manufacture and sale of generic copies of the drug based on its assertion that the drug was too likely to be abused.

198. In an interview with the *Los Angeles Times*, Purdue's senior compliance officer acknowledged that in five years of investigating suspicious pharmacies, Purdue failed to take action, even where Purdue employees personally witnessed the diversion of its drugs. The same was true of prescribers—despite its knowledge of illegal prescribing, Purdue did not report until years after law enforcement shut down a Los Angeles clinic that prescribed more than 1.1 million OxyContin tablets and that Purdue's district manager described internally as "an organized drug ring." In doing so, Purdue protected its own profits at the expense of public health and safety.

199. In 2016, the NY AG found that, between January 1, 2008 and March 7, 2015, Purdue's sales representatives, at various times, failed to timely report suspicious prescribing and continued to detail those prescribers even after they were placed on a "no-call" list.

200. As Dr. Mitchell Katz, director of the Los Angeles County Department of Health Services, said in a *Los Angeles Times* article, "[a]ny drug company that has information about physicians potentially engaged in illegal prescribing or prescribing that is endangering people's lives has a responsibility to report it." The NY AG's settlement with Purdue specifically cited the company for failing to adequately address suspicious prescribing.

201. Like Mallinckrodt and Purdue, Endo has been cited for its failure to set up an effective system for identifying and reporting suspicious prescribing. In its settlement agreement with Endo, the NY AG found that Endo failed to require sales representatives to report signs of abuse, diversion, and inappropriate prescribing; paid bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing; and failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list. The NY AG also found that, in certain cases where Endo's sales representatives detailed prescribers who were convicted of illegal prescribing of opioids, those representatives could have recognized signs of diversion and reported those prescribers but failed to do so.

2. The Manufacturer Defendants and Related Unnamed Parties Specifically Targeted Susceptible Prescribers and Vulnerable Patient Populations.

202. As a part of their deceptive marketing scheme, the Manufacturer Defendants and Related Unnamed Parties identified and targeted susceptible prescribers and vulnerable patient populations in the United States. For example, they focused their deceptive marketing on primary care doctors, who were more likely to treat chronic pain patients and prescribe them

drugs, but were less likely to be schooled in treating pain and the risks and benefits of opioids, and therefore more likely to trust the Manufacturer Defendants' and Related Unnamed Parties' misrepresentations.

203. The Manufacturer Defendants and Related Unnamed Parties also targeted vulnerable patient populations like the elderly and veterans, who tend to suffer from chronic pain. They targeted these vulnerable patients even though the risks of long-term opioid use were significantly greater for them. The 2016 CDC Guideline observed that existing evidence showed that elderly patients taking opioids suffer from elevated fall and fracture risks, greater risk of hospitalization, and increased vulnerability to adverse drug effects and interactions. The Guideline therefore concluded that there are "special risks of long-term opioid use for elderly patients" and recommended that doctors use "additional caution and increased monitoring" to minimize the risks of opioid use in elderly patients.

204. Similarly, the Manufacturer Defendants and Related Unnamed Parties specifically targeted veterans, launching APF's "Military/Veterans Pain Initiative" focused entirely on pushing opioids to veterans and members of the military, who are more likely to use anti-anxiety drugs (benzodiazepines) for post-traumatic stress disorder, which interact dangerously with opioids. The Manufacturer Defendants and Related Unnamed Parties also created publications containing misrepresentations regarding opioids that were specifically tailored to veterans, such as the APF publication *Exit Wounds.*

3. <u>The Manufacturer Defendants and Related Unnamed Parties Fraudulently Concealed Their Misconduct.</u>

205. The Manufacturer Defendants and Related Unnamed Parties made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their misrepresentations were false and misleading. As described

above, the medical community well-understood that opioids are highly addictive and dangerous. The Manufacturer Defendants and Related Unnamed Parties had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths—all of which made clear the harms from long-term opioid use and that patients have been suffering from addiction, overdose, and death in alarming numbers. More recently, the FDA and CDC have issued pronouncements based on the medical evidence that conclusively expose the falsity of the Manufacturer Defendants' and Related Unnamed Parties' misrepresentations, and Endo and Purdue have recently entered agreements with the NY AG.

206. The Manufacturer Defendants and Related Unnamed Parties concealed their deceptive marketing, including by disguising their role in the deceptive marketing of chronic opioid therapy by conspiring with Front Groups and KOLs. The Manufacturer Defendants and Related Unnamed Parties purposefully hid behind the apparent objectivity of these third-parties, who lent credibility to their false and misleading statements about the risks and benefits of long-term opioid use for chronic pain.

207. The Manufacturer Defendants and Related Unnamed Parties also hid their active role in shaping and approving the content of information and materials disseminated by these third-parties. The Manufacturer Defendants and Related Unnamed Parties exerted considerable influence on these promotional and "educational" materials in private emails, correspondence, and meetings with KOLs, Front Groups, and public relations companies. For example, painknowledge.org, which is run by the NIPC, did not disclose Endo's involvement. Other Manufacturer Defendants and Related Unnamed Parties, such as Purdue and Janssen, ran similar websites that masked their own roles.

208. In addition, the Manufacturer Defendants and Related Unnamed Parties distorted or omitted material facts in their promotional materials and influenced the scientific literature to create the false appearance that these materials were accurate, truthful, and supported by objective evidence when they were not. The Manufacturer Defendants and Related Unnamed Parties mischaracterized the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. Medical professionals and patients relied on this misinformation.

209. In short, the Manufacturer Defendants and Related Unnamed Parties successfully conspired to conceal from the medical community, patients, and health care payers material facts that would have aroused suspicion of the claims set forth herein. Plaintiff did not know of the existence or scope of the Manufacturer Defendants' and Related Unnamed Parties' industry-wide fraud until recently, when allegations of their wrongdoing became widespread, nor could he have acquired such knowledge earlier through the exercise of reasonable diligence.

4. Insys Engaged in Conduct so Fraudulent That Its Former Executives Have Been Indicted.

210. In late 2016, several former Insys executives—including its former CEO and president, former vice president of sales, former national director of sales, and former vice president of managed markets—were arrested and indicted for conspiring to bribe practitioners in order to get them to prescribe Subsys. In exchange for bribes and kickbacks, the practitioners wrote illegitimate Subsys prescriptions for patients.

211. The indictment alleged that the former executives conspired to mislead and defraud health insurance providers. Specifically, the former executives established a "reimbursement unit" dedicated to obtaining prior authorization for Subsys prescriptions. Insys' reimbursement unit employees were told to inform agents of insurers and pharmacy benefit

managers that they were calling "from" or that they were "with" the doctor's office, or that they were calling "on behalf of" the doctor.

212. The indictment details a coordinated, centralized scheme by Insys to illegally drive profits. The company defrauded insurers from a call center at corporate headquarters where Insys employees, acting at the direction of Insys' former CEO and vice president of managed markets, disguised their identity and the location of their employer, and lied about patient diagnoses, the type of pain being treated and the patient's course of treatment with other medication.

### E. The Manufacturer Defendants' and Related Unnamed Parties' Misinformation Campaign Resulted in Dramatic Increases in Opioid Use, Windfall Profits, and a Public Health Crisis.

213. The Manufacturer Defendants' and Related Unnamed Parties' misrepresentations deceived and continue to deceive insurers, doctors, and patients about the risks and benefits of long-term opioid use. Studies show that many doctors and patients are not aware of or do not understand these risks and benefits. Patients often report that they were not warned they might become addicted to opioids prescribed to them. A 2015 survey of more than 1,000 opioid patients found that 4 out of 10 were not told that opioids are potentially addictive. Patients in treatment for opioid addiction across the country confirm that they were never told that they might become addicted to opioids when they started taking them, or that they could easily stop using opioids or that the opioids they were prescribed were less addictive than alternatives.

214. The Manufacturer Defendants and Related Unnamed Parties knew and should have known that their misrepresentations about the risks and benefits of long-term opioid use were false and misleading when they made them.

215. The Manufacturer Defendants' and Related Unnamed Parties' deceptive marketing scheme and their unlawful and unfair business practices caused and continue to cause

doctors to prescribe opioids for chronic pain conditions such as back pain, headaches, arthritis, and fibromyalgia. Absent the Manufacturer Defendants' and Related Unnamed Parties' deceptive marketing scheme and their unlawful and unfair business practices, these doctors would not have prescribed as many opioids to as many patients, and there would not have been as many opioids available for misuse and abuse or as much demand for those opioids.

216. The Manufacturer Defendants' and Related Unnamed Parties' deceptive marketing scheme and their unlawful and unfair business practices also caused and continue to cause United States patients to purchase and use opioids for their chronic pain believing they are safe and effective. Absent their deceptive marketing scheme, fewer patients would be using opioids long-term to treat chronic pain, and those patients using opioids would be using less of them.

217. The Manufacturer Defendants' and Related Unnamed Parties' deceptive marketing scheme and their unlawful and unfair business practices have caused and continue to cause the prescribing and use of opioids to skyrocket in the United States. The effects of sales calls on prescribers' behavior is well-documented in the literature, including a 2017 study that found that physicians ordered fewer promoted brand-name medications and prescribed more cost-effective generic versions if they worked in hospitals that instituted rules about when and how pharmaceutical sales representatives were allowed to detail prescribers. The changes in prescribing behavior appeared strongest at hospitals that implemented the strictest detailing policies and included enforcement measures. Another study involved the research of four different practices which included visits by sales representatives, medical journal advertisements, direct-to-consumer advertising, and pricing, and found that sales representatives have the strongest effect on driving drug utilization. An additional study found that doctor meetings with

sales representatives are related to changes in doctor prescribing practices and requests by physicians to add the drugs to hospitals' formularies. Manufacturer Defendants and Related Unnamed Parties necessarily expected a return on their investment in opioid marketing, and carefully calibrated promotion efforts to serve that end.

218. Opioids are the most common means of treatment for chronic pain; 20% of office visits now include the prescription of an opioid; and 4 million Americans per year are prescribed a long-acting opioid. This surge in opioid use was not fueled by any scientific developments demonstrating that opioids were safe and effective for previously unaccepted uses. Instead, it was fueled by the Manufacturer Defendants' and Related Unnamed Parties' desire to sell more drugs to reap greater profits.

219. Across the country, the Manufacturer Defendants' and Related Unnamed Parties' deceptive marketing of the abuse-deterrent properties of their opioids has been particularly effective during the past few years. One survey reports that pain specialists were more likely to recognize that OxyContin had abuse-deterrent properties and to prescribe OxyContin specifically because of those properties. Further, prescribers who knew of OxyContin's abuse-deterrent properties were using more of it than those who did not know it was an AD opioid. Although sales of AD opioids still represent only a small fraction of opioids sold (less than 5% of all opioids sold in 2015), they represent a disproportionate share of opioid sales revenue ($2.4 billion or approximately 25% in opioid sales revenue in 2015).

220. The dramatic increase in opioid prescriptions and use corresponds with the dramatic increase in the Manufacturer Defendants' and Related Unnamed Parties' spending on their deceptive marketing scheme. Their spending on opioid marketing totaled approximately $91 million in 2000. By 2011, that spending had tripled to $288 million.

221. The Manufacturer Defendants' and Related Unnamed Parties' deceptive marketing scheme worked, causing doctors to write an escalating number of opioid prescriptions. That in turn caused a correspondingly dramatic increase in opioid addiction, overdose, and death throughout the United States.

222. According to the CDC, between 1999 and 2014, sales of opioids nearly quadrupled. In 2012 alone, approximately 259 million opioid prescriptions were written in the United States. For context, the adult population of the United States is approximately 250 million. Thus, there may be nearly ten million more opioid prescriptions written each year than there are adults in the United States.

223. Countless individuals have become addicted to opioids as a result of the use of opioids for chronic-pain treatment, often with tragic results. In 2012, more than two million Americans were abusing or dependent on opioids. Since 1999, approximately 183,000 Americans died from opioid-related overdoses. In 2014, more than 60% of drug-overdose deaths nationally involved opioids. More than 62,000 Americans are believed to have fatally overdosed from opioids in 2017 alone.

224. Representing the NIH's National Institute of Drug Abuse in hearings before the Senate Caucus on International Narcotics Control in May 2014, Dr. Nora Volkow explained that "aggressive marketing by pharmaceutical companies" is "likely to have contributed to the severity of the current prescription drug abuse problem."

225. In August 2016, U.S. Surgeon General Vivek Murthy published an open letter to be sent to physicians nationwide, enlisting their help in combating this "urgent health crisis" and linking that crisis to deceptive marketing. He wrote that the push to aggressively treat pain, and the "devastating" results that followed, had "coincided with heavy marketing to doctors . . . .

[m]any of [whom] were even taught—incorrectly—that opioids are not addictive when prescribed for legitimate pain."

226. Not surprisingly, scientific evidence confirms a strong correlation between opioid prescriptions and opioid abuse. In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses." Patients receiving prescription opioids for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."

227. The FDA also has made clear that "most opioid drugs have 'high potential for abuse,'" and "the serious risks of misuse, abuse, neonatal opioid withdrawal syndrome (NOWS), addiction, overdose, and death [are] associated with the use of ER/LA opioids overall, and during pregnancy." According to the FDA, because of the "known serious risks" associated with extended-release opioid use, including "risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death," opioids should be used only "in patients for whom alternative treatment options" like non-opioid drugs have failed. (Emphasis added.)

228. Contrary to the Manufacturer Defendants' and Related Unnamed Parties' misrepresentations, most opioid addiction begins with legitimately prescribed opioids. In 2011, 71% of people who abused prescription opioids got them through friends or relatives, not from pill mills, drug dealers, or the internet. Numerous doctors and substance abuse counselors have noted that many of their patients who misuse or abuse opioids started with legitimate prescriptions, confirming the important role that doctors' prescribing habits have played in the

opioid epidemic. Treatment centers treat a substantial percentage of patients for opioid addiction.

229. Upon information and belief, the escalating number of opioid prescriptions written by doctors who were deceived by the Manufacturer Defendants' and Related Unnamed Parties' deceptive marketing scheme, along with the Manufacturer Defendants' and Related Unnamed Parties' failure to put in place appropriate procedures to ensure suspicious orders would be reported and instead, their continuing to fill orders which supplied far more opioids than were justified, caused a correspondingly dramatic increase in opioid addiction, overdose, and death.

230. Addiction has consumed the lives of countless Americans exposed to opioids prescribed by doctors either directly, from their own prescriptions, or indirectly, from prescription drugs obtained by others and found in family medicine cabinets. It is difficult to describe the lifelong struggle and costs individuals addicted to opioids will face. The desire to get drugs becomes so consuming that addicts can no longer work or care for their children, and will resort to desperate means to persuade doctors to provide their next prescription—even pulling their own teeth.

231. The total number of opioid-involved overdose deaths from 1999 to 2017 more than quadrupled, yet overdose deaths represent only the tip of the iceberg. According to 2009 data, for every overdose death that year, there were nine abuse treatment admissions, 30 emergency department visits for opioid abuse or misuse, 118 people with abuse or addiction problems, and 795 non-medical users.

232. The overprescribing of opioids for chronic pain caused by the Manufacturer Defendants' and Related Unnamed Parties' deceptive marketing scheme has also resulted in a

dramatic rise in the number of American infants who are born addicted to opioids due to prenatal exposure and suffer from neonatal abstinence syndrome. These infants face painful withdrawal and may suffer long-term neurologic and cognitive impacts.

233. The Manufacturer Defendants' and Related Unnamed Parties' creation, through false and misleading advertising and other unlawful and unfair conduct, of a virtually limitless opioid market has significantly harmed American communities. The Manufacturer Defendants' and Related Unnamed Parties' success in extending the market for opioids to new patients and chronic pain conditions has created an abundance of drugs available for non-medical and criminal use and fueled a new wave of addiction and abuse. It has been estimated that 60% of the opioids that are abused come, directly or indirectly, through doctors' prescriptions.

234. The rise in opioid addiction caused by the Manufacturer Defendants' and Related Unnamed Parties' deceptive marketing scheme has also resulted in an explosion in heroin use; because heroin is cheaper than prescription painkillers, many prescription opioid addicts migrate to heroin when they can no longer get access to or afford the pills. Manufacturer Defendants and Related Unnamed Parties also could have, and did, foresee that users who become addicted to a particular prescription opioid would migrate to another drug (including heroin) if those drugs become less expensive or more readily available. In fact, some users migrate to heroin (sometimes with fentanyl) they buy on the street. Nationally, roughly 80% of those who used heroin in the past year previously abused prescription opioids.

235. The abuse of opioids, including opioids manufactured by the Manufacturer Defendants and Related Unnamed Parties, and the resulting increase in heroin use and addiction have caused outbreaks of HIV, chronic Hepatitis C, and TTP. One researcher who has tracked 503 drug users since 2008 found that 70% of them have contracted Hepatitis C.

236. Many patients who become addicted to opioids will lose their jobs. Some will lose their homes and their families. According to a 2016 study by a Princeton economist, the increase in opioid prescriptions from 1999 to 2015 could account for roughly 20% of the decline in labor force participation for men and 25% for women. Two-thirds of the surveyed men not in the labor force said they took prescription painkillers—compared to just 20% of employed men. Many of those taking painkillers still said they experienced pain daily.

237. Some who get addicted will receive treatment, and fewer will successfully complete it; many of those patients will relapse, returning to opioids or some other drug. Of those who continue to take opioids, some will overdose—some fatally, some not. Others will die prematurely from related causes—falling or getting into traffic accidents due to opioid-induced somnolence; dying in their sleep from opioid-induced respiratory depression; suffering assaults while engaging in illicit drug transactions; or dying from opioid-induced heart or neurological disease.

238. Even when opioid users do not die from an overdose, they often require significant health care interventions. For example, in 2015, opioid use resulted in more than 30,000 hospitalizations and emergency-room visits. This represents a nearly 200% increase over the same figure from 2005.

239. Each year, opioid abuse imposes approximately $55 billion in health and social costs across the country, and it also imposes approximately $20 billion in costs for emergency and inpatient care.

240. Opioid abuse has also resulted in substantial additional social and economic costs that have destroyed countless families and ravaged communities across the United States.

241. The harms of opioid addiction and abuse have taken a particularly serious toll on older citizens. According to the AARP, the opioid-related hospitalization rate of Americans over the age of 65 has increased fivefold over the past two decades.

242. Absent the Manufacturer Defendants' and Related Unnamed Parties' deceptive marketing scheme and their unlawful and unfair business practices, the public health crisis caused by opioid misuse, abuse, and addiction in America would have been averted or much less severe.

243. While the use of opioids has taken an enormous toll on the nation and its residents, Defendants have realized blockbuster profits. In 2014 alone, opioids generated $11 billion in revenue for drug companies like the Manufacturer Defendants and Related Unnamed Parties. As of 2016, Purdue alone had earned as much as $31 billion from its promotion of OxyContin. Indeed, financial information indicates that each Defendant experienced a material increase in sales, revenue, and profits from the false and misleading advertising and other unlawful and unfair conduct described above.

**F. The Distributor Defendants Engaged in Unlawful and Unfair Misconduct.**

244. In addition to the misrepresentations by the Manufacturer Defendants and Related Unnamed Parties described above, the Distributor Defendants engaged in misconduct, including their knowing and reckless failure to prevent the rampant diversion of opioids.

1. The Distributor Defendants Had a Duty to Exercise Reasonable Care in Distributing Opioid Drugs.

245. The Distributor Defendants have duties under the common law across the country—as well as federal laws—to exercise reasonable care and not to create a foreseeable risk of harm to others. This includes duties to put in place procedures to ensure potentially

suspicious orders would be detected, reported, and not filled, instead of continuing to fill orders which supplied far more opioids than could have supplied a legitimate market.

246. The Distributor Defendants are also required to comply with the Controlled Substances Act ("CSA"), 21 U.S.C. § 801 *et seq*. and its implementing regulations, which govern the distribution and dispensing of controlled substances. Among other reasons, Congress passed the CSA to protect against "the widespread diversion of [controlled substances] out of legitimate channels into the illegal market." H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4566, 4572.

247. The CSA regulates the distribution of drugs from the manufacturing level through delivery to the patient. Opioid distributors are required to maintain effective controls against opioid diversion. They are also required to create and employ a system to identify and report suspicious orders of controlled substances to law enforcement authorities. Suspicious orders include orders of unusual size or frequency, or otherwise deviating substantially from normal patterns. To comply with these requirements, distributors must know their customers, report suspicious orders, conduct due diligence, and terminate orders if there are indications of diversion.

248. To prevent unauthorized users from obtaining opioids, the CSA created a distribution monitoring system for controlled substances based on the registration and tracking requirements imposed on distributors of controlled substances. The DEA's Automation of Reports and Consolidation Orders System ("ARCOS") is an automated drug reporting system that monitors the flow of Schedule II controlled substances from their point of manufacture through commercial distribution channels to point of sale. ARCOS accumulates data on distributors' acquisition/distribution transactions, which are then summarized into reports used by the DEA to identify any diversion of controlled substances into illicit channels of distribution.

Everyone registered to distribute ARCOS reportable controlled substances is supposed to report acquisition and distribution transactions to the DEA.

249. Acquisition and distribution transaction reports provide data on each acquisition to inventory, identifying whether it is, for example, by purchase, transfer, or return from a customer, and each reduction from inventory, identifying whether it is, for example, by sale, transfer, theft, destruction, or seizure by government agencies. *See* 21 U.S.C. § 827(d)(l); 21 C.F.R. §§ 1304.33(e), (d). Inventory that has been lost or stolen is also reported separately to the DEA within one business day of discovery.

250. In addition to filing acquisition and distribution transaction reports, registrants are required to maintain complete and accurate records of each substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of. *See* 21 U.S.C. §§ 827(a)(3), 1304.2l (a), 1304.22(b). It is unlawful to fail to abide by the recordkeeping and reporting requirements.

251. Distributors of controlled substances also are required to maintain effective controls against diversion of controlled substances into other than legitimate medical, scientific and industrial channels. When determining if a distributor has provided effective controls, the DEA Administrator refers to the security requirements set forth in the regulations, which provide standards for the physical security controls and operating procedures necessary to prevent diversion. *See* 21 C.F.R. § 1301.71.

252. Because the Distributor Defendants were already purporting to monitor and report on opioid transactions, their utter failure to take reasonable precautions to ensure the accuracy of their reports was an inexcusable breach of common law duty.

2. <u>The Distributor Defendants Knowingly or Negligently Facilitated Widespread Diversion of Opioids.</u>

253. Opioid diversion has been a widely publicized problem for years. Numerous publications, studies, agencies, and professional organizations have highlighted the dangerous rates of opioid abuse and overdose across the country.

254. To address the problem of opioid diversion, the DEA has provided guidance to distributors in the form of publications, agency actions, and other documents on the requirements of suspicious order reporting.

255. For over a decade, the DEA has conducted one-on-one briefings with distributors regarding downstream customer sales and prudent due diligence steps. The DEA provided distributors with information on controlled substance distribution patterns and trends, including data on order volume, order frequency, and the ratio of controlled to non-controlled purchases. The Distributor Defendants were also given case studies, legal findings against other registrants, and ARCOS profiles of their customers whose previous purchases may have reflected suspicious ordering patterns. The DEA highlighted "red flags" that distributors should look for in order to identify potential diversion. The DEA implemented this initiative to help distributors understand their duties with respect to diversion control.

256. In addition, the DEA has hosted numerous conferences to provide registrants with updated information about diversion trends and regulatory changes affecting the drug supply chain, the distributor initiative, and suspicious order reporting. The Distributor Defendants attended these conferences, which also provided opportunities to ask questions and raise concerns.

257. The DEA also participated in numerous meetings and events with the Healthcare Distribution Management Association (HDMA), which is now known as the Healthcare Distribution Alliance (HDA)—an industry trade association for drug wholesalers and

distributors. DEA representatives have provided guidance concerning suspicious order monitoring to the HDA, which has published guidance documents for members on suspicious order monitoring, reporting requirements, and diversion of controlled substances.

258. In addition, the DEA Office of Diversion Control sent letters dated September 27, 2006 and December 27, 2007 to all registered distributors providing guidance on suspicious order monitoring of controlled substances and the responsibilities of registrants to conduct due diligence on customers of controlled substances.

259. The September 27, 2006 letter reminded registrants that they are required by law to exercise due diligence to avoid filling orders that may be diverted into the illicit market. It explained that as part of the legal obligation to maintain effective controls against diversion, distributors are required to exercise due care in confirming the legitimacy of all orders prior to filling. It also described indicia of diversion, including orders of excessive quantities of a limited variety of controlled substances, disproportionate ratios of controlled substances to non-controlled prescription drugs, excessive quantities of a limited variety of controlled substances in combination with lifestyle drugs, and orders of the same controlled substance from multiple distributors. The letter went on to describe what questions should be answered by a customer when attempting to determine whether an order is suspicious.

260. On December 27, 2007, the Office of Diversion Control sent a follow-up letter to DEA registrants providing guidance and reiterating the legal requirements. The letter reminded registrants that suspicious orders must be reported promptly and simply on monthly transaction reports. It also advised that registrants must perform independent analyses of suspicious orders prior to the sales to determine if diversion appears likely, and that filing suspicious order reports and then completing the sales does not absolve registrants from legal responsibility. Finally, the

letter directed registrants to review a recent DEA action that addressed criteria in determining suspicious orders and the obligation to maintain effective controls against diversion.

261. The Distributor Defendants also were notified by their own industry group, the HDMA, which published Industry Compliance Guidelines entitled "Reporting Suspicious Orders and Preventing Diversion of Controlled Substances," which emphasized the responsibilities of each member of the supply chain in distributing controlled substances. These industry guidelines further stated that, "At the center of a sophisticated supply chain, distributors are uniquely situated to perform due diligence in order to help support the security of controlled substances they deliver to their customers."

262. The Distributor Defendants have acknowledged the magnitude of the problem and their legal responsibilities to prevent diversion, and they have issued statements assuring the public they were supposedly undertaking a duty to curb the opioid epidemic.

263. For example, a Cardinal executive claimed that it uses "advanced analytics" to monitor its supply chain and that Cardinal was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."

264. Similarly, McKesson has publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders" and that it is "deeply passionate about curbing the opioid epidemic in our country."

265. Based on such assurances, in addition to the obligations imposed by law, the Distributor Defendants had a duty to protect the public against diversion from their supply chains. Despite these types of statements, however, the Distributor Defendants have knowingly or negligently allowed diversion. As a result of their misconduct, the Distributor Defendants

have paid numerous civil fines and other penalties to state and federal regulators, including actions by the DEA for violations of the CSA.

266. For example, as part of the $35 million dollar file for failure to report suspicious orders of controlled substances, the Department of Justice stated that Mallinckrodt "did not meet its obligations to detect and notify DEA of suspicious orders of controlled substances such as oxycodone, the abuse of which is part of the current opioid epidemic. These suspicious order monitoring requirements exist to prevent excessive sales of controlled substances, like oxycodone . . . . Mallinckrodt's actions and omissions formed a link in the chain of supply that resulted in millions of oxycodone pills being sold on the street[.]" Mallinckrodtr likewise admitted that, "[a]s a registrant under the CAS, Mallinckrodt had a responsibility to maintain effective controls against, diversion, including a requirement that it review and monitor these sales and report suspicious orders to the DEA."

267. In another widely publicized reprimand, in 2008, Cardinal paid a $34 million penalty to settle allegations by the DEA about opioid diversion taking place at seven of its warehouses around the United States. In 2012, Cardinal reached an administrative settlement with the DEA relating to opioid diversion between 2009 and 2012 in Florida. And in December 2016, the U.S. Department of Justice announced another $34 million settlement with Cardinal for civil penalties under the CSA. In connection with the investigations of Cardinal, the DEA uncovered evidence that Cardinal's own investigator had warned Cardinal against selling opioids to a particular pharmacy in Florida that was suspected of opioid diversion. Cardinal did nothing to notify the DEA or to cease the supply of drugs to the suspect pharmacy. Instead, Cardinal's opioid shipments to the pharmacy *increased*—to almost 2 million doses of oxycodone in one year, while other comparable pharmacies received approximately 69,000 doses per year.

268. Similarly, in May 2008, McKesson entered into a settlement agreement with the DEA to settle claims that it had failed to maintain effective controls against diversion of controlled substances. McKesson allegedly failed to report suspicious orders from rogue Internet pharmacies around the country, resulting in the diversion of millions of doses of controlled substances. McKesson agreed to pay a $13.25 million civil fine. It was subsequently revealed that McKesson's system for detecting "suspicious orders" from pharmacies was so ineffective that at one of its facilities in Colorado, between 2008 and 2013, it had filled more than 1.6 million orders, but reported just 16 orders from a single customer as suspicious. In 2015, McKesson was again alleged to have "suspicious order reporting practices for controlled substances." In 2017, McKesson agreed to pay a record $150 million civil penalty to the federal government to settle opioid diversion claims relating to diversion at 12 distribution centers in 11 states.

269. In 2007, AmerisourceBergen lost its license to send controlled substances from a distribution center amid allegations that it was not controlling shipments of prescription opioids to Internet pharmacies. In 2012, AmerisourceBergen was again investigated for failing to protect against diversion of controlled substances into non-medically necessary channels. It has been reported that the U.S. Department of Justice subpoenaed AmerisourceBergen for documents in connection with a grand jury proceeding seeking information on the company's "program for controlling and monitoring diversion of controlled substances into channels other than for legitimate medical, scientific and industrial purposes."

270. Despite these and other penalties and settlements with law enforcement authorities over the past decade, the Distributor Defendants have continued to allow diversion of opioids to maximize their revenue.

3. The Distributor Defendants' Misconduct Facilitated the Opioid Epidemic.

271. Although the Distributor Defendants had the ability and duty to prevent opioid diversion, they continued to allow it, which enabled the opioid crisis to reach epidemic proportions.

272. The Distributor Defendants have supplied huge quantities of prescription opioids in the United States with actual or constructive knowledge that the opioids were ultimately being consumed for non-medical purposes. Many of these shipments should have been stopped or investigated as suspicious orders, but the Distributor Defendants negligently or intentionally failed to do so.

273. The Distributor Defendants knew or should have known that the amounts of opioids that they allowed to flow were far in excess of what could be consumed for medically-necessary purposes in the relevant communities.

274. The Distributor Defendants negligently or intentionally failed to adequately control their supply lines to prevent diversion. A reasonably-prudent distributor of Schedule II controlled substances would have protected against the danger of opioid diversion by: taking greater care in hiring, training, and supervising employees; providing greater oversight, security, and control of supply channels; more carefully scrutinizing the pharmacists and doctors who were purchasing large quantities of commonly-abused opioids in amounts greater than the populations in those areas would warrant; investigating demographic factors concerning the increasing demand for narcotic painkillers in certain communities; proactively providing information to pharmacies and retailers about opioid diversion; and at a bare minimum, following applicable statutes, regulations, professional standards, and guidance from government agencies.

275. The Distributor Defendants made insufficient efforts to monitor or to perform due diligence to ensure that the controlled substances they had furnished were not being diverted to illegal uses.

276. On information and belief, the Distributor Defendants compensated certain of their employees, at least in part, based on the volume of their sales of opioids, thus improperly creating incentives that contributed to opioid diversion and the resulting epidemic of opioid abuse.

277. It was reasonably foreseeable to the Distributor Defendants that their conduct in flooding the market with highly-addictive opioids would allow opioids to fall into the hands of addicts, criminals, vulnerable populations, and other unintended users. It was also reasonably foreseeable to the Distributor Defendants that, when unintended users gained access to opioids, tragic preventable injuries would result, including addiction, overdose, and death throughout the United States.

278. The Distributor Defendants knew or should have known that the opioids being diverted from their supply chains would contribute to the opioid epidemic and would create access to opioids by unauthorized users, which, in turn, would perpetuate the cycle of addiction, demand, and illegal transactions.

279. The Distributor Defendants knew or should have known that a substantial amount of the opioids dispensed in and to the United States were being dispensed based on invalid or suspicious prescriptions. It is foreseeable that filling suspicious orders for opioids will cause harm to individual pharmacy customers, third-parties, and the United States.

280. The Distributor Defendants were aware of widespread prescription opioid abuse throughout the country, but they nevertheless persisted in a pattern of distributing commonly

abused and diverted opioids in geographic areas and in such quantities, and with such frequency that they knew or should have known these commonly abused controlled substances were not being prescribed and consumed for legitimate medical purposes.

281. The use of opioids by American citizens who were addicted or who did not have a medically-necessary purpose to use opioids could not occur without the knowing cooperation and assistance of the Distributor Defendants. If the Distributor Defendants had implemented and enforced effective controls to guard against diversion, the United States and its citizens would have avoided significant injury.

282. The Distributor Defendants made substantial profits from their distribution of opioids in America, including opioids that they knew or should have known were being diverted to improper channels.

## G. United States Purchasers of Health Care Insurance Have Sustained Substantial Harm as a Result of All Defendants' Misconduct.

283. Health insurance is an individual or group policy that provides coverage for hospital, medical, surgical, and/or prescription drug benefits.

284. The Manufacturer and Distributor Defendants' misconduct has increased Plaintiff's cost of private health insurance in the United States.

285. In 2014, United States residents paid more than $2.56 *trillion* for health care, of which $875 billion was spent on private health insurance. Throughout the country, health care costs are increasing at a rate far above core inflation. From 1991 to 2014, Americans spent an average of 4.9% more per year on personal, health care-related expenses.

286. Insurance premiums—the fees paid to get and keep insurance—have risen at an even more alarming clip. From 2001 to 2014, American enrollees in private health insurance have spent 5.6% more per year, increasing the total amount spent per person from $2,250 in

2001 to $4,551 in 2014. The average family of four enrolled in private health insurance pays around $18,000 per year to cover premiums, co-pays, and other health care related expenses.

287. Many American employees obtain health insurance through an employer. Providers of group health care insurance include the various BlueCross BlueShield entities, Humana, Aetna, Cigna, Anthem, and UnitedHealthcare.

288. Other Americans obtain individual health insurance. These Americans typically buy individual health insurance when they do not have access to an employer plan and do not qualify for public health insurance like Medicaid or Medicare. Providers of individual health insurance similarly include the various BlueCross BlueShield entities, Humana, Aetna, Cigna, Anthem, and UnitedHealthcare.

289. Group participants may pay all or part of the premium directly, or their employers may pay all or part of the premium directly. Individual purchasers (or members of their family) pay the entire premium directly. The "deductible" in a health-insurance plan is the amount the insured must pay each period (usually annually) before insurance starts to cover health care costs. A "co-pay" is a flat amount the insured pays per claim, such as a doctor visit or prescription. "Co-insurance" is the percentage of a bill that the insured pays under some plans after the deductible is met. Deductibles and co-payments often are higher under individual plans.

290. As a direct and proximate result of the conduct described herein, natural and corporate persons have sustained losses and injuries in the form of higher premiums, deductibles, and co-payments/co-insurance. Health care insurers in the United States have paid (and expect to continue to pay) substantial amounts for opioid prescriptions that would never have been prescribed and/or filled absent all Defendants' misconduct, and have also paid (and expect to continue to pay) substantial amounts for treatment of individuals who became addicted to

opioids and/or who became addicted to heroin or other drugs because of opioid use. Many of those individuals who became addicted to opioids—or who became addicted to heroin or other drugs because of opioid use—would never have become addicted or even received access to opioids absent Defendants' conduct described herein. These insurers have also paid for numerous other costs proximately caused by all Defendants' conduct, including care for babies born addicted to opioids, emergency-room treatments, and other claims.

291. Plaintiff purchasers of private health insurance have been damaged as a result of paying prices that are higher as a direct result of all Defendants' misconduct. Health insurers are easily able to—and do—pass higher costs onto their insureds. Premiums in health-insurance markets do not reflect individual differences in costs, meaning that *all* insureds bear higher costs inflicted by the highest-risk insureds.

292. Insurers typically charge premiums based on assigned rate classes, a pool of insured individuals with similar health status. Because the premium charged is uniform for the entire risk class, excessive claims experienced by others raise premiums for everyone. This empirical reality makes economic sense. Insurers cannot know *ex ante* if an individual insured will take and become addicted to opioids, with the corresponding costs that ensue for that patient. So insurers charge every insured a higher premium—including the majority of insureds who never take opioids—to pay for the risk of future, opioid-related claims.

293. This is partially because insured patients with opioid abuse or dependence diagnoses cost health insurers more than average patients. In 2015, total annual per-patient charges (the costs of providing a health service) and allowed amounts (the maximum an insurer will pay for a covered health service) for services for patients with opioid abuse and dependence diagnoses were 550% higher than for the average insured patient.

294. Thus, as the opioid crisis has barreled forward across the country, so has the pressure on insurance companies to raise premiums. Indeed, by one estimate, private insurance claims related to opioid dependence rose by an astonishing 3,200% nationwide from 2007 to 2014, with the brunt of this burden falling on those aged 19 to 35. This makes sense in light of the demonstrated increase in opioid-related emergency room visits and treatment center admissions, along with the growth in the percentage of privately insured Americans over this period. Similarly, professional charges and allowed amounts grew by over 1,000% for patients diagnosed with opioid abuse or dependence from 2011 to 2015, further increasing insurance companies' incentive to increase their customers' rates.

295. The costs that all Defendants' conduct inflicted on the insurance market cannot be and have not been confined to opioid users because of such risk pooling. Empirical evidence evaluated by leading economists confirms this common-sense conclusion. In addition, many of the costs that all Defendants have inflicted on the health system involve risks that insurers may not refuse to cover as a matter of law and regulation, since "all states have mandated certain benefits that must be included in the health insurance package of that state, most commonly for substance abuse." Jonathan Gruber and Helen Levy, *The Evolution of Medical Spending Risk*, JOURNAL OF ECONOMIC PERSPECTIVES, 23(4), pp. 25-48, at 32 (2009).

## H. All Defendants and the Related Unnamed Parties Acted Wantonly, Willfully, Outrageously, and with Reckless Disregard for the Consequences of Their Actions.

296. When engaging in the conduct described herein, all Defendants acted wantonly, willfully, outrageously, and with reckless disregard for the consequences of their actions.

297. All Defendants knew and should have known about these harms that their unlawful and unfair business practices have caused and continue to cause in the United States. The Manufacturer Defendants and Related Unnamed Parties closely monitored their sales and

the habits of prescribing doctors. Their sales representatives, who visited doctors and attended CMEs, knew which doctors were receiving their messages and how they were responding. They knew—and, indeed, intended—that their misrepresentations would persuade doctors across the country to prescribe and patients to use their opioids for chronic pain. Likewise, the Distributor Defendants knew of the risks and signs of diversion, and yet failed to take action that would have prevented or mitigated opioid diversion. All Defendants also had access to, and carefully watched, government and other data that tracked the explosive rise in opioid use, addiction, injury, and death.

298. At all relevant times, all Defendants and the Related Unnamed Parties knew that the likely consequences of their actions would be that millions of individuals would become addicted to opioids and other drugs, which in turn would destroy countless families and communities across the nation, while imposing tremendous medical and other costs that would be borne by all purchasers of health insurance.

299. Despite this knowledge, Defendants and the Related Unnamed Parties engaged in the conduct described herein for the purpose of obtaining billions of dollars in windfall profits, while destroying the lives of countless Americans.

300. The Manufacturer Defendants' and Related Unnamed Parties' actions are not excused by the fact that their drug labels may have allowed or did not exclude the use of opioids for chronic pain. FDA approval of opioids for certain uses did not give license to misrepresent the risks and benefits of opioids. Indeed, the Manufacturer Defendants' and Related Unnamed Parties' misrepresentations were directly contrary to pronouncements by and guidance from the FDA based on the medical evidence and their own labels.

301. Nor is Defendants' causal role broken by the involvement of doctors. The Manufacturer Defendants' marketing efforts were ubiquitous and highly persuasive. Their deceptive messages tainted virtually every source doctors could rely on for information and prevented them from making informed treatment decisions. The Manufacturer Defendants also were able to harness and hijack what doctors wanted to believe—namely, that opioids represented a means of relieving their patients' suffering and of practicing medicine more compassionately.

302. While insurance companies may refuse to cover ineffective or dangerous treatments, they too were misled by Defendants' pervasive campaign to convince the health care industry that opioids were effective and necessary for long-term pain management. Insurers paid Defendants for the care ordered by patients' doctors, as well as for the resulting costs of addiction: treatment, emergency-room care, and other claims. Those costs were ultimately passed along to Plaintiff and all Class members.

## FACTS SPECIFIC TO PLAINTIFF

303. Plaintiff is a natural person and resident and citizen of the State of Illinois.

304. Plaintiff purchases health insurance for himself and his family through a group health plan offered by Plaintiff's employer, from Blue Cross Blue Shield of Illinois.

## CLASS ALLEGATIONS

305. **Class Definition**: Plaintiff brings this action pursuant to Fed. R. Civ. P. 23(b)(2) and (3) on behalf of himself and a Class of similarly situated individuals, defined as follows:

> All persons (including natural persons and entities) who purchased and paid premiums for health insurance policies in the United States governed by U.S. law from 1996 through the present; and all persons who paid for any portion of employer-provided health insurance governed by the laws of the United States from 1996 through the present.

Excluded from the Class are: (1) any Judge or Magistrate presiding over this action and members of their families; (2) Defendants, Defendants' subsidiaries, parents, successors, predecessors, and any entity in which the Defendants or their parents have a controlling interest and their current, former, purported, and alleged employees, officers, and directors; (3) counsel for Plaintiff and Defendants; (4) persons who properly execute and file a timely request for exclusion from the Class; (5) the legal representatives, successors, or assigns of any such excluded persons; and (6) all persons who have previously had claims similar to those alleged herein finally adjudicated or who have released their claims against Defendants.

306. **Numerosity**: The exact number of Class members is unknown to Plaintiff at this time, but it is clear that individual joinder is impracticable. As of 2014, the Centers for Medicare and Medicaid Services estimated that over 196 million people in the United States enrolled in private health insurance. Ultimately, the Class members will be easily identified through third-party business records.

307. **Commonality and Predominance**: There are many questions of law and fact common to the claims of Plaintiff and the Class, and those questions predominate over any questions that may affect individual Class members. Common questions for the Class include, but are not necessarily limited to the following:

- whether Defendants made material misrepresentations regarding the benefits and risks of their products;
- whether Defendants acted intentionally with respect to the foregoing;
- whether Defendants were negligent in the distribution of their products;
- whether Defendants acted in violation of state and federal law;
- whether the Class is entitled to restitution and/or disgorgement, in addition to, or as a substitute for, damages; and
- whether Plaintiff is entitled to damages and/or injunctive relief.

308. **Typicality**: Plaintiff's claims are typical of the claims of all the other Class members. Plaintiff and the Class members sustained substantially similar damages as a result of Defendants' uniform wrongful conduct, based upon the same interactions that were made uniformly with Plaintiff and the public.

309. **Adequate Representation**: Plaintiff will fairly and adequately represent and protect the interests of the other Class members. Plaintiff has retained counsel with substantial experience in prosecuting complex litigation and class actions. Plaintiff and his counsel are committed to vigorously prosecuting this action on behalf of the Class members and have the financial resources to do so. Neither Plaintiff nor his counsel has any interest adverse to those of the other Class members.

310. **Policies Generally Applicable to the Class**: Defendants have acted and failed to act on grounds generally applicable to Plaintiff and the other Class members, requiring the Court's imposition of uniform relief to ensure compatible standards of conduct toward the Class.

311. **Superiority**: This case is also appropriate for class certification because class proceedings are superior to all other available methods for the fair and efficient adjudication of this controversy as joinder of all parties is impracticable. The damages suffered by individual Class members will likely be relatively small compared to the burden and expense of individual prosecution of the complex litigation necessitated by Defendants' actions. Thus, it would be virtually impossible for individual Class members to obtain effective relief from Defendants' misconduct. Even if Class members could sustain such individual litigation, it would still not be preferable to a class action, because individual litigation would increase the delay and expense to all parties due to the complex legal and factual controversies presented in this Complaint. By contrast, a class action presents far fewer management difficulties and provides the benefits of

single adjudication, economies of scale, and comprehensive supervision by a single Court. Economies of time, effort, and expense will be fostered and uniformity of decisions ensured.

312. Plaintiff reserves the right to revise the Class Definition and Class Allegations based on further investigation, including facts learned in discovery.

## CAUSES OF ACTION

### COUNT I:
### Violations of Consumer Protection Laws
### (Against All Defendants)

313. Plaintiff repeats, reiterates, and realleges each and every allegation contained in the paragraphs above as if fully set forth herein.

314. Defendants are subject to the various consumer protection laws in every part of the United States in which they conduct business, including:

- Alabama's Unfair Trade Practices Code, Ala. Code 1975 § 8-19-5, *et seq.*;
- Alaska's Unfair Trade Practices and Consumer Protection Act, Alaska Stat. § 45.50.471;
- Arizona's Consumer Fraud Act, A.R.S. §§ 44-1521-34, *et seq.*;
- Arkansas's Deceptive Trade Practices Act, Ark. Code Ann. § 4-88-107;
- California's Unfair Competition Law, Business and Professions Code §§ 17200, *et seq.*;
- Colorado's Consumer Protection Act, Colo. Rev. Stat. 1975 § 6-1-105(1), *et seq.*;
- Connecticut's Unfair Trade Practices Act, C.G.S. § 42-110A-110Q;
- Delaware's Consumer Fraud Act, Del. Code Ann. tit. 6, § 2513;
- The District of Columbia's Consumer Protection Procedures Act, DC Official Code §§ 28-3901, *et seq*.;
- Florida's Deceptive and Unfair Trade Practices Act, §§ 501.201-.213;
- Georgia's Fair Business Practices Act, C.G.S. O.C.G.A. § 10-1-390, *et seq*.;

- Hawaii's Uniform Deceptive Trade Practices Act, H.R.S. § 480-1, *et seq*.;
- Idaho's Consumer Protection Act, Idaho Code Ann. § 48-603, *et seq*.;
- Illinois's Consumer Fraud Act, 815 ILCS 505/2, *et seq*.;
- Indiana's Deceptive Consumer Sales Act, I.C. § 24-5-0.5-3(a), *et seq*.;
- Iowa's Private Right of Action for Consumer Frauds Act, Iowa Code Ann. § 714H.1, *et seq*.;
- Kansas's Consumer Protection Act, K.S.A. § 50-626, *et seq*.;
- Kentucky's Consumer Protection Act, Ky. Rev. Stat. Ann. § 367.110, *et seq*.;
- Louisiana's Unfair Trade Practices and Consumer Protection Act, La. Stat. Ann. § 51:1405, *et seq*.;
- Maine's Unfair Trade Practices Act, Me. Rev. Stat. tit. 5, § 205, *et seq*.;
- Maryland's Consumer Protection Act, Md. Code Ann., Com. Law § 13-301, *et seq*.;
- Minnesota's Deceptive Trade Practices Act, Minn. Stat. Ann. § 325D.44, *et seq*.;
- Mississippi's Consumer Protection Act, Miss. Code. Ann. § 75-24-5, *et seq*.;
- Missouri's Merchandising Practices Act, Mo. Rev. Stat. Ann. § 407.010, *et seq*.;
- Montana's Unfair Trade Practices and Consumer Protection Act, Mont. Code Ann. § 30-14-103, *et seq*.;
- Nebraska's Uniform Deceptive Trade Practices Act, Neb. Rev. Stat. § 87-302, *et seq*.;
- Nevada's Deceptive Trade Practices Act, N.R.S. § 598.0915, *et seq.*;
- New Hampshire's Regulation of Business Practices for Consumer Protection Act, N.H. Rev. Stat. Ann. § 358-A, *et seq.*;
- New Jersey's Consumer Fraud Act, N.J.S.A. § 56:8-1, *et seq*.;
- New Mexico's Unfair Trade Practices Act, N.M. Stat. § 57-12, *et seq.*;

- New York's General Business Law § 349;
- North Carolina's N.C. Gen. Stat. § 75-1.1, *et seq*.;
- North Dakota's Unlawful Sales or Advertising Practices Act, N.D.C.C. § 51-15-02, *et seq*.;
- Ohio's Consumer Sales Protection Act, O.R.C. § 1345, *et seq*.;
- Oklahoma's Deceptive Trade Practices Act, Okla. Stat. tit. 78 § 53, *et seq*.;
- Puerto Rico's Consumer Protection, 26 L.P.R.A. § 2701, *et seq*.;
- Rhode Island's Unfair Trade Practice and Consumer Protection Act, R.I. Gen. Laws § 6-13.1, *et seq*.;
- South Carolina's Unfair Trade Practice Act, S.C. Code § 39-5-10(a), *et seq*.;
- South Dakota's Deceptive Trade Practices and Consumer Protection Act, S.D. Codified Laws § 37-24-1, *et seq.*;
- Tennessee's Consumer Protection Act, T.C.A. § 47-18-104, *et seq*.;
- Texas's Deceptive Trade Practices Act, Consumer Protection Act, Tex. Bus. & Com. Code §§ 17.41–17.63;
- Utah's Deceptive Commerce and Trade, Utah Ann. Code § 13-11a-1, *et seq*.;
- Utah's Consumer Sales Practices Act, Utah Ann. Code § 13-11-1, *et seq.*;
- Vermont's Consumer Protection Act, VT. STAT. ANN. tit. 9, §§ 2451, *et seq*.;
- Virginia's Consumer Protection Act, Va. Code Ann. § 59.1-196, *et seq*.;
- Washington's Consumer Protection Act, Wash. Rev. Code § 19.86.020, *et seq*.;
- West Virginia's Consumer Protection Act, W. Va. Code § 46A-6-104, *et seq*.;
- Wisconsin's Deceptive Trade Practices Act, WIS. STAT. §§ 100.18, *et seq*.;
- Wyoming's Consumer Protection Act, Wyo. Stat. §§ 40-12-101, *et seq*.;

315. Plaintiff brings this Count on behalf of all members of the Class who are or have been residents of the United States at any relevant time under the laws of the respective Class members' individual places of residence.

316. The consumer protection laws of the United States prohibit Defendants from engaging in deceptive acts of practices in the course of their business.

317. Plaintiff and Class members are persons protected by the consumer protection laws.

318. Defendants' business practices as described in this Complaint are unfair, are deceptive, and violate the consumer protection laws of the United States law because the practices complained of deceived doctors, insurers, and consumers in every part of the United States, led to the sale of opioids that should not have been sold, and thereby caused Plaintiff and Class members to pay higher insurance premiums. These practices concealed, suppressed, and omitted material facts in the manufacture, marketing, sales and distribution of Defendants' opioid products.

319. The Manufacturer Defendants knew and should have known at the time of making or disseminating these statements, or causing these statements to be made or disseminated, that such statements were false and deceptive. Their omissions, which are fraudulent, unfair, and deceptive in their own right, render even seemingly truthful statements about opioids false and deceptive. All of this conduct, separately and collectively, was likely to deceive United States doctors, who prescribed opioids based on the Manufacturer Defendants' deception, and insurers who purchased, or covered the costs for the purchase of, opioids for chronic pain.

320. In addition, the Distributor Defendants were in the position to implement effective business practices to guard against diversion of the highly-addictive opioid products they sell and

distribute. They repeatedly purported to have done so. But those representations were untrue. Instead, they profited off the opioid epidemic by flouting anti-diversion laws, while burdening American consumers by their conduct and profiting from the sale of prescription opioids in quantities that far exceeded the number of prescriptions that could reasonably have been used for legitimate medical purposes, despite having notice or actual knowledge of widespread opioid diversion from prescribing records, pharmacy orders, field reports, and sales representatives.

321. The Distributor Defendants' acts in violation of the law are unfair and deceptive business practices that constitute independent violations of the consumer protection laws, including the Distributor Defendants' filling of suspicious or invalid orders for prescription opioids at both the wholesale and retail level; failing to maintain effective controls against opioid diversion; failing to operate an effective system to disclose suspicious orders of controlled substances; failing to report suspicious orders of controlled substances; failing to reasonably maintain necessary records of opioid transactions; and deliberately ignoring questionable and/or obviously invalid prescriptions and filling them anyway—all while purporting to have world-class and compliant systems, controls, and practices.

322. All Defendants' fraudulent, unlawful, unfair, and/or deceptive activity alleged herein caused insurers to pay for ineffective and dangerous treatments, as well as the increased costs associated with opioid addiction. Those costs were passed on to Plaintiff and members of the Class in the form of increased insurance premiums.

323. As a direct and proximate result of the foregoing acts and practices, all Defendants have received, or will receive, income, profits, and other benefits, which they would not have received if they had not engaged in the violations described in this Complaint.

**COUNT II:**
**Violations of the Racketeering Influenced and Corrupt Organizations Act,**
**18 U.S.C. §§ 1961, *et seq.***

**(Against All Defendants)**

324. Plaintiff repeats, reiterates, and realleges each and every allegation contained in the paragraphs above as if fully set forth herein.

325. At all relevant times, each Defendant is and has been a "person" within the meaning of 18 U.S.C. § 1961(3), because they are capable of holding, and do hold, "a legal or beneficial interest in property."

326. Section 1962(c) makes it "unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity . . . " 18 U.S.C. § 1962(c). Each Defendant conducted and participated in the affairs of an enterprise through a pattern of racketeering activity, in violation of 18 U.S.C. § 1962(c).

**A. The Enterprise**

327. Defendants formed an association-in-fact Enterprise and participated in the affairs of the Enterprise to increase the market for opioids through a pattern of racketeering activity. The Enterprise consists of (1) the Manufacturer Defendants, including their employees and agents, (2) the Related Unnamed Parties, including their employees and agents, (3) Front Groups, including their employees and agents, (4) the KOLs, and (5) the Distributor Defendants, including their employees and agents. The Enterprise's purpose was to fabricate a new market for opioids in chronic pain treatment and sell as many opioid products as possible through deception and willfully ignoring requirements to curtail the illegal drug market that the Enterprise's conduct created.

328. To accomplish this purpose, the Enterprise systematically misrepresented to the general public, doctors, and insurers the risks of using opioids for chronic pain, and flouted

requirements to investigate and prevent the ensuing waive of suspicious orders. The Manufacturer Defendants, Related Unnamed Parties, Front Groups, KOLs, and Distributor Defendants all conducted and participated in the affairs of the Enterprise by distributing false statements through the wires or mail or by violating the Controlled Substances Act. This campaign of illegality and misinformation translated into profits for all Defendants, and funding and payments to Front Groups and KOLs.

329. The participants in the Enterprise are systematically linked through contractual relationships, financial ties, and continued coordination of activities, spearheaded by the Manufacturer Defendants. There is regular communication between the Manufacturer Defendants, Related Unnamed Parties, Distributor Defendants, Front Groups, and KOLs in which information is shared. This communication typically occurs, and continues to occur, through the use of the wires and mail in which the participants share information regarding overcoming objections to the use of opioids for chronic pain.

330. The Distributor Defendants were willing participants in, and beneficiaries of, the Enterprise's campaign of deception. Distributor Defendants profited from the Enterprise's newly-expanded opioid market, and furthered the Enterprise's goal of profiting from that market by flouting legal requirements to report suspicious ordering. By the Distributor Defendants' violating the CSA's requirements to prevent diversion, all Defendants were able to profit from both the legal and illegal drug markets created by the Enterprise's success in establishing the long-term opioid treatment market and the ensuing addiction crisis. Distributor Defendants were aware of the campaign of deception engineered by the Manufacturing Defendants, Related Unnamed Parties, KOLs, and Front Groups, but sought only to profit from the Enterprise's deception.

331. The Distributor Defendants are intimately connected with the Manufacturer Defendants and Related Unnamed Parties through their industry organization, the HDA. According to the HDA's website, the HDA's executive committee includes an executive from each Distributor Defendant. Each Manufacturer Defendant and Related Unnamed Party is also a member of HDA.

332. HDA specifically advertises its benefits as a forum for meeting with distributors. The Distributor Defendants used membership in the HDA as an opportunity to create working relationships with Manufacturer Defendants. HDA, in turn, is a member of PCF. Each Manufacturer Defendant, or a related company, is a member of PCF.

333. Together, Defendants and Related Unnamed Parties lobbied state governments and Congress to undermine enforcement and legal limitations that would otherwise have interfered with increased opioid sales. Between 2006 and 2015, the PCF spent more than $740 million lobbying to influence local, state and federal governments, including on opioid-related measures. The HDA and PCF lobbied for passage of the Ensuring Patient Access and Effective Drug Enforcement Act, which hobbled the DEA's ability to suspend or revoke registrations, permitting Distributor Defendants to further the Enterprise's goal of increasing opioid sales without regard to legal requirements or the effects on Americans. Defendants' coordination through the HDA, PCF, and lobbying activities—while not racketeering activity—evidence Defendants' knowledge of the structure of the Enterprise and purposeful participation in it.

334. At all relevant times, Front Groups were knowing and willing participants in the Enterprise's conduct, and reaped benefits from that conduct. Each Front Group also knew, but did not disclose, that the other Front Groups were engaged in the same scheme. But for the Enterprise's unlawful scheme, Front Groups would have had the incentive to disclose the deceit

by the Manufacturer Defendants to their members and constituents. By failing to disclose this information, Front Groups perpetuated the Enterprise's scheme and reaped substantial benefits.

335. At all relevant times, KOLs were knowing and willing participants in the Enterprise's conduct, and reaped profits from that conduct. The Manufacturer Defendants selected KOLs solely because they favored the aggressive treatment of chronic pain with opioids. The Manufacturer Defendants' support helped these doctors become respected industry experts. And, as they rose to prominence, these doctors touted the benefits of opioids to treat chronic pain, repaying the Manufacturer Defendants by advancing their marketing goals. The KOLs also knew, but did not disclose, that the other KOLs and Front Groups were engaged in the same scheme, to the detriment of Plaintiff and Class members. But for the Enterprise's unlawful scheme, KOLs would have been incentivized to disclose the deceit, and to protect their patients and the patients of other physicians. By failing to disclose this information, KOLs perpetuated the Enterprise's scheme, and reaped substantial benefits.

336. Furthermore, as public scrutiny and media coverage have focused on how opioids have ravaged communities throughout the United States, the Front Groups and KOLs did not challenge the Manufacturer Defendants' misrepresentations, seek to correct their previous misrepresentations, terminate their role in the Enterprise, nor disclose publicly that the risks of using opioids for chronic pain outweighed their benefits.

337. The Front Groups and KOLs participated in the conduct of the Enterprise, sharing the common purpose of marketing opioids for chronic pain and, through a pattern of racketeering activity including multiple instances of wire and mail fraud, knowingly made material misstatements to physicians, consumers, and the general public in furtherance of the scheme, including that:

- it was rare, or there was a low risk, that the Manufacturer Defendants' and Related Unnamed Parties' opioids could lead to addiction;[60]

- the signs of addiction were actually signs of undertreated pain, known as "pseudoaddiction," that should be treated by more opioids;[61]

- doctors and patients could increase opioid dosages indefinitely without risk;[62] and

- long-term opioid use improved patients' function and quality of life.[63]

338. Without the misrepresentations of the Front Groups and KOLs, who were perceived as neutral and scientific, the Defendants and Related Unnamed Parties alone could not have accomplished the purposes of the Enterprise.

339. During the time period described in this Complaint, the Manufacturer Defendants and Related Unnamed Parties exerted control over the Enterprise and participated in the operation and management of the affairs of the Enterprise, directly or indirectly, in the following ways:

- The Manufacturer Defendants and Related Unnamed Parties created a body of deceptive and unsupported medical and popular literature about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;

- The Manufacturer Defendants and Related Unnamed Parties selected, cultivated, promoted, and paid the KOLs based solely on their willingness to communicate and distribute the Manufacturer Defendants' and Related Unnamed Parties' messages about the use of opioids for chronic pain;

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60 APF, *Treatment Options: A Guide for People Living with Pain*, *supra* ¶ 85(c) APF, *Policymaker's Guide*, discussed *supra* ¶ 85(i).

61 Fishman, *Responsible Opioid Prescribing*, *supra* ¶ 110(a); APF, *Treatment Options*, *supra* ¶ 110(h).

62 APF, *Treatment Options*, *supra* ¶ 129(c); Endo, *Understanding Your Pain: Taking Oral Opioid Analgesics* (Russell Portenoy, ed.), *supra* ¶ 129(e); APF, *Policymakers' Guide*, *supra* ¶ 129(h).

63 Fishman, *Responsible Opioid Prescribing*, *supra* ¶ 156(e); APF, *Treatment Options*, *supra* ¶ 156(f), NIPC website & educational programs, *supra* ¶ 156(g), (h).

- The Manufacturer Defendants and Related Unnamed Parties provided substantial opportunities for KOLs to participate in research studies on topics the Manufacturer Defendants and Related Unnamed Parties suggested or chose, with the predictable effect of ensuring that many favorable studies appeared in the academic literature;

- The Manufacturer Defendants and Related Unnamed Parties paid KOLs to serve as consultants or on their advisory boards and to give talks or present CMEs, typically over meals or at conferences;

- The Manufacturer Defendants and Related Unnamed Parties disseminated many of their false, misleading, imbalanced, and unsupported statements through unbranded materials that appeared to be independent publications from Front Groups;

- The Manufacturer Defendants and Related Unnamed Parties sponsored CME programs put on by Front Groups that focused exclusively on the use of opioids for chronic pain;

- The Manufacturer Defendants and Related Unnamed Parties developed and disseminated pro-opioid treatment guidelines;

- The Manufacturer Defendants and Related Unnamed Parties encouraged Front Groups to disseminate their pro-opioid messages to groups targeted by the Manufacturer Defendants and Related Unnamed Parties, such as veterans and the elderly, and then funded that distribution;

- The Manufacturer Defendants and Related Unnamed Parties concealed their relationship to and control of Front Groups and KOLs from the State and the public at large;

- The Manufacturer Defendants and Related Unnamed Parties intended that Front Groups and KOLs would distribute, through the U.S. mail and interstate wire facilities, promotional and other materials that claimed opioids could be safely used for chronic pain; and

- The Manufacturer Defendants, Related Unnamed Parties, Front Groups, and KOLs minimized the fact that opioids were being diverted due to the Enterprise's misconduct.

340. During the time period described in this Complaint, the Distributor Defendants conducted and participated in the affairs of the Enterprise in the following ways:

- The Distributor Defendants violated the Controlled Substances Act and caused massive diversion of opioids by failing to investigate suspicious orders;

- The Distributor Defendants violated the Controlled Substances Act by failing to maintain adequate controls against diversion of prescription opioids;

- The Distributor Defendants refused to identify, investigate or report suspicious orders of prescription opioids being diverted into the illicit drug market; and
- The Distributor Defendants made false and misleading statements attempting to minimize their responsibility for preventing diversion and representing that they complied with the law.

341. The scheme had a hierarchical decision-making structure that was headed by the Manufacturer Defendants. The Manufacturer Defendants controlled representations made about their drugs, and doled out funds to Front Groups and payments to KOLs to ensure that their representations were consistent with the Manufacturer Defendants' messaging nationwide. Front Groups were dependent on the Manufacturer Defendants for their financial support, and KOLs were professionally dependent on the Manufacturer Defendants for the development and promotion of their careers. The Distributor Defendants worked hand-in-hand with the Manufacturer Defendants to limit government enforcement and increase sales of opioids through industry groups like the HDA and the PCF.

342. For the foregoing reasons, all Defendants, Related Unnamed Parties, Front Groups, and KOLs were each willing participants in the Enterprise, had a common purpose and interest in furthering opioid prescribing and increasing sales of opioids without regard to diversion, and functioned within a structure designed to effectuate the common purpose.

343. The scheme devised and implemented by all Defendants, as well as other members of the Enterprise, amounted to a common course of conduct intended to encourage the prescribing and use of opioids for chronic pain and thereby secure payment from insurers for Defendants' opioids. The scheme was a continuing course of conduct, and many aspects of it continue through to the present.

344. The Enterprise was intended to and did affect interstate commerce, in that the statements made by the members of the Enterprise were passed through the wires or mail over

state lines, and that the Enterprise increased sales of opioids through the channels of interstate commerce.

345. The impacts of the Enterprise continue to be felt, as opioids continue to be prescribed and used for chronic pain. Plaintiff continues to pay for the fallout from the Enterprise as insurers pass on the costs of opioid addiction and treatment.

**B. Pattern of Racketeering Activity**

346. Racketeering activity includes mail fraud, 18 U.S.C. § 1341, and wire fraud, 18 U.S.C. § 1343. 18 U.S.C. § 1961.

347. The Manufacturer Defendants, Related Unnamed Parties, Front Groups, and KOLs all made misrepresentations detailed above in service of a scheme to deceive which was intended to, and did, deceive consumers, doctors and insurers about the safety and efficacy of opioid use. All were passed through the wires and/or mail, and constituted predicate acts within the meaning of RICO, including:

- The dissemination via wires and mail of APF's *Treatment Options* beginning in 2007 and continuing afterward, which misrepresented the risks of addiction, promulgated the false concept of pseudoaddiction, falsely represented that doctors and patients could increase opioid dosages without risk, and falsely represented that long-term opioid use could improve patients' quality of life;

- The dissemination via wires and mail of APF's *Policymaker's Guide* beginning in 2011 and continuing afterward, which misrepresented the risks of addiction and falsely represented that doctors and patients could increase opioid dosages indefinitely without risk;

- The dissemination via wire of Endo's pamphlet, edited by Russel Portenoy, *Understanding Your Pain*, available on Endo's website throughout the time period described in this Complaint, which falsely represented that doctors and patients could increase opioid dosages without risk;

- The dissemination via wires and mail of *Responsible Opioid Prescribing*, beginning in 2007 and afterward, which promulgated the false concept of pseudoaddiction and falsely represented that long-term opioid use could improve patients' quality of life; and

- The dissemination via wires and mail of the misrepresentations and false statements described above in paragraphs 63-66, 85, 110, 120, 129, 138-139, 142, 145, 156, and 171-172.

348. The Distributor Defendants engaged in the violations of the law detailed above to enable the Enterprise to profit from its deceptive creation of the expanded market for opioids. Distributor Defendants' activities were coordinated and planned with the Manufacturer Defendants, as evidenced by coordinated lobbying efforts to weaken DEA enforcement. Distributor Defendants, through their relationships with the Manufacturer Defendants, were aware of the Enterprise's deceptive activity and sought only to enable the Enterprise to profit from it. To do so, Distributor Defendants engaged in the following predicate acts:

- Mallinckrodt's violations of the CSA and federal law concerning the distribution of controlled substances—described above in paragraphs 179-194 and 266—which resulted in fines, penalties or settlements with the DEA;

- Cardinal's violations of the CSA and federal law concerning the distribution of controlled substances—described above in paragraph 267—in 2008, 2012, and 2016, which resulted in fines, penalties or settlements with the DEA;

- McKesson's violations of the CSA and federal law concerning the distribution of controlled substances—described above in paragraph 268—in 2008 and 2017 which resulted in fines, penalties or settlements with the DEA; and

- AmerisourceBergen's violations of the CSA and federal law concerning the distribution of controlled substances—described above in paragraph 269—in 2007 and 2012 that resulted in penalties and an investigation by the Department of Justice.

349. Many of the precise dates of the Defendants' coordination have been hidden and cannot be alleged without access to the Defendants' records. Indeed, an essential part of the successful operation of the Enterprise alleged herein depended upon secrecy.

350. The Manufacturer Defendants', Related Unnamed Parties', the Front Groups', and KOLs' deceptive activities were coordinated and planned in advance, as evidenced by the Front Groups' and KOLs' misleading statements described above that were supported, funded, or compensated by the Manufacturer Defendants. Many of the precise dates of the Manufacturer

Defendants', Related Unnamed Parties', Front Groups', and KOLs' agreement to violate RICO, however, have been hidden and cannot be alleged without access to the Manufacturer Defendants', the Related Unnamed Parties', the Front Groups', and the KOLs' books and records. Indeed, for the deception to be successful, the coordination between the Manufacturer Defendants, Related Unnamed Parties, and the seemingly-independent Front Groups and KOLs had to remain secret.

351. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including doctors, insurers, and consumers. The Manufacturer Defendants, Related Unnamed Parties, the Front Groups, and the KOLs calculated and intentionally crafted the opioids marketing scheme to increase and maintain their increased profits, without regard to the effect such behavior had on Plaintiff and Class members. The Distributor Defendants knowingly and intentionally assisted the Enterprise in cashing in on the market that the Enterprise's deceptive conduct created.

352. By intentionally misrepresenting the risks and benefits of using opioids for chronic pain, subsequently failing to disclose such practices, and profiting off of the legal and illegal market that deception created, the Manufacturer Defendants, the Distributor Defendants, Related Unnamed Parties, the Front Groups, and the KOLs engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

**C. Damages**

353. Defendants' violations of law and their pattern of racketeering activity have directly and proximately caused Plaintiff and Class members to be injured in their business or property in the form of increases in insurance premiums.

354. But for Defendants', Related Unnamed Parties', the Front Groups', and the KOLs' racketeering activities, Plaintiff and Class members would not have paid the increases in insurance premiums associated with the opioid epidemic. It was foreseeable that Defendants' racketeering activities would result in insurers' losses in the form of (1) overpayment for ineffective drugs, and (2) massive healthcare costs associated with opioid addiction, and that those costs would be passed on to Plaintiff and Class members.

355. Plaintiff and Class members seek all legal and equitable relief permitted by RICO, including equitable relief, actual damages, treble damages, and attorneys' fees. 18 U.S.C. § 1964.

**COUNT III:**
**Conspiracy to Violate the Racketeering Influenced and Corrupt Organizations Act, 18 U.S.C. §§ 1961, *et seq.***
**(Against All Defendants)**

356. Plaintiff repeats, reiterates, and realleges each and every allegation contained in the paragraphs above as if fully set forth herein.

357. At all relevant times, each Defendant is and has been a "person" within the meaning of 18 U.S.C. § 1961(3), because they are capable of holding, and do hold, "a legal or beneficial interest in property."

358. Section 1962(d) makes it unlawful for "any person to conspire to violate" Section 1962(c), among other provisions. *See* 18 U.S.C. § 1962(d).

359. Defendants conspired to violate RICO, as alleged more fully above, by agreeing to conduct and participate in the affairs of the Enterprise detailed above.

**A. The Enterprise**

360. Plaintiff incorporates by reference paragraphs 327 through 345 above concerning the Enterprise.

361. Each Defendant, Related Unnamed Party, KOL, and Front Group was aware of the scope and nature of the Enterprise and intended to participate in it. The Manufacturer Defendants and Related Unnamed Parties directed and supported the KOLs and Front Groups in disseminating false and misleading information about the necessity and risks of opioids, such as the publications supported and financed by the Manufacturer Defendants and Related Unnamed Parties referenced in Count II above. The Distributor Defendants were aware of this deception through their relationships with the Manufacturer Defendants and Related Unnamed Parties, including through the HDA and PCF's lobbying efforts, and agreed to serve the Enterprise's goals of profiting from this deception.

**B. Pattern of Racketeering Activity**

362. Plaintiff incorporates by reference Count II above concerning the Enterprise. Defendants agreed to conduct and participate in the affairs of the Enterprise detailed in those paragraphs.

**C. Damages**

363. Plaintiff incorporates by reference paragraphs 353 through 355 above concerning the damages caused by the Enterprise.

**COUNT IV:**
**Public Nuisance**
**(Against All Defendants)**

364. Plaintiff repeats, reiterates, and realleges each and every allegation contained in the paragraphs above as if fully set forth herein.

365. Under the laws of the sovereign entities of the United States, public nuisances are those nuisances which tend to the immediate annoyance of the public in general, are injurious to the public health or safety, or tend greatly to corrupt the manners and morals of the public.

366. Defendants are prohibited from creating of perpetuating public nuisances that affect rights common to some subset of the general population in a given community.

367. Each Defendant, acting individually and in concert, has created or assisted in the creation of a condition that is injurious to the health and public safety, and interferes with the comfortable enjoyment of life and property of entire communities or neighborhoods or of any considerable number of persons across the United States.

368. The public nuisance is substantial and unreasonable, and has harmed those who have come in contact with it. All Defendants' actions caused and continue to cause the public health epidemic described above, and that harm outweighs any offsetting benefit.

369. The Manufacturer Defendants knew and should have known that their promotion of opioids was false and misleading and that their deceptive marketing scheme and other unlawful, unfair, and fraudulent actions would create or assist in the creation of the public nuisance—*i.e.*, the opioid epidemic. The Manufacturer Defendants' actions were, at the very least, a substantial factor in opioids becoming widely available and widely used. Their actions were, at the very least, a substantial factor in deceiving doctors and patients about the risks and benefits of opioids for the treatment of chronic pain.

370. The Distributor Defendants knew and should have known that the rampant diversion of opioids that they enabled would create or assist in the creation of the public nuisance—*i.e.*, the opioid epidemic. The Distributor Defendants' actions were, at the very least, a substantial factor in the widespread diversion of opioids throughout the United States.

371. Without all Defendants' actions, opioid use, misuse, abuse, and addiction would not have become so widespread, and the opioid epidemic that now exists would have been averted or much less severe.

372. All Defendants' actions have increased the cost of insuring individuals, and Plaintiff and Class members—who pay insurance premiums—have suffered a special injury.

373. The public nuisance—*i.e.*, the opioid epidemic—created, perpetuated, and maintained by all Defendants can be abated and further recurrence of such harm and inconvenience can be abated.

374. Plaintiff requests an order providing for abatement of the public nuisance that Defendants created or assisted in the creation of, and enjoining Defendants from future violations of the laws of the United States.

**COUNT V:**
**Unjust Enrichment**
**(Against All Defendants)**

375. Plaintiff repeats, reiterates, and realleges each and every allegation contained in the paragraphs above as if fully set forth herein.

376. To the detriment of Plaintiff and Class members, all Defendants have been, and continue to be, unjustly enriched as a result of the unlawful and/or wrongful conduct alleged herein.

377. All Defendants have voluntarily accepted and retained the inflated prices paid for their opioid products with full knowledge that they were not lawfully entitled to it.

378. Plaintiff and Class members bear the costs of the benefits conveyed to all Defendants in the form of increased insurance premiums.

379. Between Defendants and Plaintiff/Class members, it would be unjust for Defendants to retain the benefits attained by their wrongful actions.

380. All Defendants have been unjustly enriched, in the form of inflated prices, at the expense of Plaintiff and Class members who are entitled in equity to disgorgement and restitution of Defendants' wrongful profits, revenue, and benefits, to the extent, and in the

amount deemed appropriate by the Court, and any other relief the Court deems just and proper to remedy Defendants' unjust enrichment.

**COUNT VI:**
**Negligence**
**(Against All Defendants)**

381. Plaintiff repeats, reiterates, and realleges each and every allegation contained in the paragraphs above as if fully set forth herein.

382. Each Defendant has a duty to exercise reasonable care in manufacturing and distributing highly dangerous medications in the United States.

383. Defendants owe that duty to Plaintiff and Class members. Defendants' profits as manufacturers and distributors are inextricably bound with the industry of health insurance, and any reasonably prudent manufacturer is aware of the basic mechanics of the insurance industry by which costs are passed on to others in a risk pool through premiums.

384. The Manufacturer Defendants knew and should have known that misleading doctors and insurers about the safety and efficacy of opioids for long-term pain treatment would cause significant costs, not just to those for whom opioids were an ineffective and dangerous treatment, but to insurers that absorb healthcare costs, and thus ultimately to insurance customers. Similarly, the Distributor Defendants knew and should have known that allowing diversion of opioids would cause significant costs to consumers, insurers, and insurance customers.

385. The Manufacturer Defendants breached their duty to Plaintiff and Class members through their false and misleading promotion of opioids and their deceptive marketing scheme, misrepresenting the nature of the drugs and aggressively promoting them for chronic pain.

386. The Distributor Defendants breached their duty to Plaintiff and Class members to conform their behavior to the legal standard of reasonable conduct under the circumstances, in

the light of the apparent risks, as well as through their failure to comply with state and federal laws protecting against diversion of controlled substances.

387. All Defendants' conduct caused opioids to become widely available and widely used, and Defendants' actions were, at the very least, a substantial factor in the widespread abuse of opioids. Without Defendants' actions, opioid use, misuse, abuse, and addiction would not have become so widespread, and the opioid epidemic that now exists would have been averted or much less severe.

388. As described above, Defendants' breach caused and proximately caused damages to Plaintiff and Class members.

**COUNT VII:**
**Civil Conspiracy**
**(Against All Defendants)**

389. Plaintiff repeats, reiterates, and realleges each and every allegation contained in the paragraphs above as if fully set forth herein.

390. The Manufacturer Defendants have engaged, and continue to engage, in a massive marketing campaign to misstate and conceal the risks of treating chronic pain with opioids. Their aggressive marketing campaign enabled Manufacturer Defendants to overcome the longstanding medical consensus that opioids were unsafe for the treatment of chronic pain and resulted in a significant increase in the number of opioids prescribed nationwide.

391. In response to and in conjunction with this increased demand, the Distributor Defendants continuously supplied prescription opioids. These transactions occurred despite the Distributor Defendants having actual or constructive knowledge that they were habitually breaching their common law and statutory duties.

392. None of the Defendants would have succeeded in profiting so significantly from the opioid epidemic without the concerted conduct of the other parties.

393. As a result of the concerted action between the Manufacturer Defendants and the Distributor Defendants, the laws of the United States were continually violated by the provision of opioids through the supply chain.

394. Defendants formed an agreement to commit the aforementioned unlawful acts.

395. Defendants commissioned the aforementioned unlawful acts.

396. Plaintiff and Class members incurred damages—in the form of increased health insurance premiums—as a result of Defendants' tortious acts pursuant to the aforementioned conspiracy.

## PRAYER FOR RELIEF

397. Plaintiff, on behalf of himself and the Class, respectfully requests that this Court enter an Order:

398. Declaring that the claims brought by Plaintiff may be maintained as a class action;

399. Declaring that Defendants have engaged in unlawful, unfair, and deceptive business acts and practices in violation of the consumer protection laws of the United States;

400. Ordering Defendants to pay restitution of any money acquired by their unlawful, unfair, and deceptive business practices;

401. Declaring that Defendants have violated RICO;

402. Ordering Defendants to divest themselves of any interest in the Enterprise and restraining Defendants from participating in further violations of RICO;

403. Declaring that Defendants have created a public nuisance and enjoining Defendants to abate the public nuisance that they created.

404. Declaring that Defendants have been unjustly enriched by their conduct;

405. Ordering Defendants to pay restitution of all benefits and disgorge all profits unjustly retained by Defendants;

406. Declaring that Defendants have acted negligently;

407. Ordering Defendants to pay all damages caused to Plaintiff and Class members by their negligent actions;

408. Declaring that Defendants have engaged in an unlawful civil conspiracy;

409. Ordering Defendants to pay all damages caused to Plaintiff and Class members by their acts pursuant to their civil conspiracy;

410. Awarding treble and punitive damages as appropriate;

411. Awarding injunctive relief as necessary to protect the interests of Plaintiff and the Class;

412. Awarding Plaintiff and the members of the Class their reasonable litigation expenses and attorneys' fees;

413. Awarding Plaintiff and the members of the Class pre- and post-judgment interest, to the extent allowable; and

414. Awarding such other and further relief as equity and justice may require.

**JURY TRIAL DEMANDED**

415. Plaintiff demands a jury trial for all claims so triable.

Respectfully submitted,

**ERIC HESTRUP**, individually and on behalf of all others similarly situated,

Dated: December 27, 2019

By: /s/ *Seth A. Meyer*
One of Plaintiff's Attorneys

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**Pro Hac Vice* admission to be sought

*Counsel for Plaintiff and the Putative Class*

ILND 44 (Rev. 09/07/18)

# CIVIL COVER SHEET

The ILND 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. ***(See instructions on next page of this form.)***

## I. (a) PLAINTIFFS

ERIC HESTRUP, individually and on behalf of all others similarly situated

**(b)** County of Residence of First Listed Plaintiff _____
*(Except in U.S. plaintiff cases)*

**(c)** Attorneys *(firm name, address, and telephone number)*

Keller Lenkner LLC
150 N. Riverside Plaza, Suite 4270, Chicago, IL 60066

## DEFENDANTS

MALLINCKRODT PLC, et. al

County of Residence of First Listed Defendant _____
*(In U.S. plaintiff cases only)*

*Note: In land condemnation cases, use the location of the tract of land involved.*

Attorneys *(if known)*

## II. BASIS OF JURISDICTION *(Check **one** box, only.)*

- ☐ 1 U.S. Government Plaintiff
- ☒ 3 Federal Question *(U.S. Government not a party)*
- ☐ 2 U.S. Government Defendant
- ☐ 4 Diversity *(Indicate citizenship of parties in Item III.)*

## III. CITIZENSHIP OF PRINCIPAL PARTIES *(For Diversity Cases Only.)*

*(Check **one** box, only for plaintiff and **one** box for defendant.)*

| | PTF | DEF | | PTF | DEF |
|---|---|---|---|---|---|
| Citizen of This State | ☐ 1 | ☐ 1 | Incorporated *or* Principal Place of Business in This State | ☐ 4 | ☐ 4 |
| Citizen of Another State | ☐ 2 | ☐ 2 | Incorporated *and* Principal Place of Business in Another State | ☐ 5 | ☐ 5 |
| Citizen or Subject of a Foreign Country | ☐ 3 | ☐ 3 | Foreign Nation | ☐ 6 | ☐ 6 |

## IV. NATURE OF SUIT *(Check **one** box, only.)*

**CONTRACT**
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

**TORTS**

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 530 General
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

**PRISONER PETITIONS**
- 510 Motions to Vacate Sentence
- 530 General
- 535 Death Penalty

**Habeas Corpus:**
- 540 Mandamus & Other
- 550 Civil Rights
- 555 Prison Condition
- 560 Civil Detainee – Conditions of Confinement

**LABOR**
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

**PROPERTY RIGHTS**
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent – Abbreviated New Drug Application
- ☐ 840 Trademark

**OTHER STATUTES**
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729 (a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☒ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 485 Telephone Consumer Protection Act (TCPA)
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

**REAL PROPERTY**
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

**CIVIL RIGHTS**
- ☐ 440 Other Civil Rights
- 441 Voting
- 442 Employment
- 443 Housing/ Accommodations
- 445 Amer. w/Disabilities - Employment
- 446 Amer. w/Disabilities - Other
- 448 Education

**BANKRUPTCY**
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

**IMMIGRATION**
- ☐ 462 Naturalization Application
- ☐ 463 Habeas Corpus - Alien Detainee (Prisoner Petition)
- ☐ 465 Other Immigration Actions

**FORFEITURE/PENALTY**
- 625 Drug Related Seizure of Property 21 USC 881
- 690 Other

**SOCIAL SECURITY**
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

**FEDERAL TAXES**
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

## V. ORIGIN *(Check **one** box, only.)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation ☐ 8 Multidistrict Litigation Direct File

## VI. CAUSE OF ACTION

(Enter U.S. Civil Statute under which you are filing and write a brief statement of cause.)

28 U.S.C. 1322(d)(2)

## VII. PREVIOUS BANKRUPTCY MATTERS

(For nature of suit 422 and 423, enter the case number and judge for any associated bankruptcy matter previously adjudicated by a judge of this Court. Use a separate attachment if necessary.)

## VIII. REQUESTED IN COMPLAINT:

☐ Check if this is a **class action** Under rule 23, F.R.C.V.P. **Demand $**

**Check Yes only if demanded in complaint.**
**Jury Demand:** ☐ Yes ☒ No

## IX. RELATED CASE(S) IF ANY *(See instructions)*

Judge _____ Case Number _____

**X. Is this a previously dismissed or remanded case?** ☐ **Yes** ☒ **No** **If yes, Case #** **Name of Judge**

**Date**
December 27, 2019

**Signature of attorney of record**
Seth A. Meyer